Annex XXXII

USER'S GUIDE

A. Introduction

1) The OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) sets out standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The purpose of this guide is to advise the Veterinary Authorities of OIE Member Countries on how to use the *Terrestrial Code*.

2) The standards in the *Terrestrial Code* should be used by the Veterinary Authorities of Member Countries to set up measures providing for early detection, reporting and control of pathogenic agents, including zoonotic, in terrestrial animals (mammals, birds and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.

3) Correctly applied, the OIE standards provide for animal production and trade in animals and animal products to take place with an optimal level of animal and veterinary public health safety, based on the most recent scientific information and available techniques.

B. *Terrestrial Code* content

1) Key terms and expressions used more than once in the *Terrestrial Code* are defined in the Glossary. When reading and using the *Terrestrial Code*, the Veterinary Authorities of Member Countries should be aware of the definitions given in the Glossary. Defined terms appear in italics. In the on-line version of the *Terrestrial Code*, a hyperlink leads to the relevant definition.

2) The term '(under study)' is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not yet been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not yet part of the *Terrestrial Code*.

3) The standards in the chapters of Section 1 of the *Terrestrial Code* are designed for the implementation of measures for the diagnosis, surveillance and notification of pathogenic agents, including procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country or zone.

4) The standards in the chapters of Section 2 of the *Terrestrial Code* are designed for conducting import risk analysis used by an importing country in the absence of OIE trade standards or to justify import measures more stringent than existing OIE trade standards.

5) The standards in the chapters of Section 3 of the *Terrestrial Code* are designed for the establishment, maintenance and evaluation of quality Veterinary Services, including veterinary legislation. These standards are to assist the Veterinary Services of OIE Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certificates.

6) The standards in the chapters of Section 4 of the *Terrestrial Code* are designed for the implementation of measures for the prevention and control of pathogenic agents, including through animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsectisation and general hygiene precautions. Some chapters address the specific sanitary measures to be applied for the collection and processing of semen and embryos of animals.

7) The standards in the chapters of Section 5 of the *Terrestrial Code* are designed for the implementation of general sanitary measures for trade, in particular veterinary certification and the measures applicable by the exporting, transit and importing countries, especially Members of the World Trade Organization (WTO). It also includes a range of model veterinary certificates to be used as a harmonised basis for international trade.

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8) The standards in the chapters of Section 6 of the *Terrestrial Code* are designed for the implementation of preventive measures in animal production systems, to assist OIE Member Countries in meeting their veterinary public health objectives. This includes ante- and port-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.

9) The standards in the chapters of Section 7 of the *Terrestrial Code* are designed for the implementation of animal welfare measures, including those at the level of production, transport, and slaughter or killing. Additional standards address the animal welfare aspects of stray dog population control and the use of animals in research and education.

10) The standards in each of the chapters of Sections 8 to 15 of the *Terrestrial Code* are designed to prevent the agents of OIE listed diseases, infections or infestations from being introduced into an importing country, taking into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity. These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to 15 each relate to the host species of the pathogenic agent: multiple species or single species of the families apidae, aves, bovidae, equidae, leporidae, caprinae and suidae. Some chapters include specific measures to prevent and control the infections of global concern. Although the OIE aims to include a chapter for each OIE listed disease, not all OIE listed diseases have been covered yet by a specific chapter. This is work in progress, depending on available scientific knowledge and the priorities set by the World Assembly.

C. Specific issues

1) Notification

Chapter 1.1. describes Member Countries' obligations under the OIE Organic Statutes. Although only listed and emerging diseases, as prescribed in Chapter 1.1., are compulsorily notifiable, Member Countries are encouraged to provide information to the OIE on any animal health event of epidemiological significance.

Chapter 1.2. describes the criteria for the inclusion of a disease, infection or infestation in the OIE List and gives the updated list. Diseases are divided into nine categories, depending of the host species of the agents.

2) Diagnostic tests and vaccines

The use of specified diagnostic tests and vaccines in *Terrestrial Code* chapters is recommended with a reference to the relevant section in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*). Chapter 1.3. provides a table summarising the recommended diagnostic tests for OIE listed diseases. Facilities responsible for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3) Prevention and control

Chapters 4.5. to 4.11. describe the measures which should be implemented during collection and processing of semen and embryos of animals, including micromanipulation and cloning, in order to prevent animal health risks, especially when trading these commodities. Although this relates principally to OIE listed diseases or infections, general standards applies to all health risks. Moreover, in Chapter 4.7. diseases that are not listed diseases are mentioned for the information of OIE Member Countries.

Chapter 4.14. addresses the specific issue of the control of bee diseases and some of its trade implications. This chapter should be read in conjunction with the specific bee disease chapters in Section 9.

Chapter 6.4. is designed for the implementation of general biosecurity measures in intensive poultry production, whereas Chapter 6.5. gives an example of a specific on-farm prevention and control plan for the non-listed food borne pathogen *Salmonella* in poultry, including standards for introduction of live poultry and hatching eggs.

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Chapter 6.11. deals specifically with the zoonotic risk associated with the movements of non-human primates and gives standards for certification, transportation and import conditions of these animals.

4) Trade requirements

An OIE Member Country may authorise the importation of animals or animal products into its territory under conditions more or less restrictive than those recommended by the *Terrestrial Code*. However, where the conditions are more restrictive, they should be scientifically justified by a risk analysis conducted in accordance with OIE standards, as described in Chapter 2.1. For Members of the WTO to meet their obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), international trade animal health measures should be based on an OIE standard or an import risk analysis.

Chapters 5.1. to 5.3. describe the obligations and ethics in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters, which also provide guidance for informal mediation by the OIE.

The OIE aims to include, at the beginning of each chapter relating to a specific agent in Sections 8 to 15 an article listing the commodities that are considered safe for trade regardless of the status of the country or zone for the agent in question. This is a work in progress and some chapters do not yet contain articles listing safe commodities. Where such a list is present, there should be no trade restrictions applied to the listed commodity in relation to the agent in question.

5) International veterinary certificates

An international veterinary certificate is an official document drawn up by the Veterinary Authority of an exporting country in accordance with Chapter 5.1. and Chapter 5.2., describing the animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services, including the ethical approach to the provision of veterinary certificates and their history in meeting their notification obligations, is essential in providing assurance to trading partners regarding the safety of exported animals and products.

International veterinary certificates underpin international trade and provide assurances to the importing country regarding the health status of the animals and products imported. The measures prescribed should take into account the health status of both exporting and importing countries and be based upon the standards in the *Terrestrial Code*.

The following steps should be taken when drafting international veterinary certificates:

a) List the diseases for which the importing country is justified in seeking protection in regards to its own disease status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control or eradication programmes;

b) For commodities capable of transmitting these diseases through international trade, the importing country should apply the articles addressing the commodity in question in the relevant disease specific chapters, adapted to the disease status of the exporting country, zone or compartment. Such status should be established according to the articles of the relevant disease chapter, or to Chapter 1.4. when there are no such articles.

c) When preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. As stated in Article 5.2.2., international veterinary certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements.

d) Chapters 5.10. to 5.12. contain model certificates as a further guidance to Member Countries and should be used as a baseline.

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6) Guidance notes for importers and exporters

To provide a clear understanding of trade requirements, it is advisable that Veterinary Authorities of OIE Member Countries prepare 'guidance notes' to assist importers and exporters. These notes should identify and explain the trade conditions, including the measures to be applied before and after export, during transport and unloading, relevant legal obligations and operational procedures. Exporters should also be reminded of the International Air Transport Association rules governing air transport of animals and animal products. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination.

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Annex XXXIII

Original: English

December 2012–January 2013

REPORT OF THE MEETING OF THE OIE ELECTRONIC *AD HOC* GROUP ON THE LISTING OF *TAENIA SOLIUM*

December 2012–January 2013

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The OIE *ad hoc* Group on the Listing of *Taenia solium* (the *ad hoc* Group) met electronically during December 2012 and January 2013.

The members of the *ad hoc* Group are presented at Annex 1.

Background

In response to the OIE *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents proposal to delist porcine cysticercosis (*Taenia solium*), in the report of their September 2012 meeting, the Terrestrial Animal Health Standards Commission (Code Commission) had asked Members to advise on this proposal and, if the proposal to delist the diseases is not supported, to provide scientific information relevant to the OIE criteria to justify continued listing.

Following discussions with the President of the Code Commission, the International Trade Department convened an electronic *ad hoc* Group, in December 2012, to assess *Taenia solium* against the OIE criteria for listing. The *ad hoc* Group included three participants, two from the *ad hoc* Group on Zoonotic Parasites and an expert on *Taenia solium*.

The *ad hoc* Group undertook an assessment of porcine cysticercosis (*Taenia solium*) against the criteria for the inclusion of diseases, infections and infestations on the OIE list, provided in Chapter 1.2. of the *Terrestrial Animal Health Code* (*Terrestrial Code*).

The assessment undertaken by the *ad hoc* Group against each of the criteria is provided below.

Criteria 1: International spread of the agent (via live animals, their products or fomites) has been proven.

> ***Ad hoc Group comment:*** *There is some international spread of human cysticercosis, mainly through immigration of people from endemic countries. However, documented cross-border movement of infected pigs is lacking.*

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AND

Criteria 2: **At least one country has demonstrated freedom or impending freedom from the *disease, infection* or *infestation* in populations of susceptible *animals,* based on the animal health surveillance provisions of the *Terrestrial Code,* in particular those contained in Chapter 1.4.**

Ad hoc Group comment: *Many countries are at negligible risk for porcine cysticercosis; it is endemic mainly in only a few regions (e.g. Latin America, Africa, South and Southeast Asia). Within these endemic regions, the number of affected countries is small. In Sub-Saharan Africa, the number of affected countries is considerable. In these endemic countries the public health importance of human cysticercosis is considerable.*

AND

Criteria 3:

a) Natural transmission to humans has been proven, and human infection is associated with severe consequences

Ad hoc Group comment: *This has been well-documented; neurocysticercosis is considered as a major risk for epilepsy, especially in developing countries.*

OR

b) The *disease* has been shown to cause significant morbidity or mortality in domestic *animals* at the level of a country or a *zone*.

Ad hoc Group comment: *Pig infections are generally non-clinical.*

OR

c) The *disease* has been shown to, or scientific evidence indicates that it would cause significant morbidity or mortality in *wild animal* populations.

Ad hoc Group comment: *Unknown, but because* T. solium *is restricted to suids and humans, morbidity in wild pigs presumably is insignificant.*

AND

Criteria 4: **A reliable means of detection and diagnosis exists and a precise *case* definition is available to clearly identify *cases* and allow them to be distinguished from other *diseases, infections* and *infestations***

Ad hoc Group comment: *Post-mortem examination of pigs is not highly sensitive. However, it is useful for screening out carcasses with the most dangerous infection levels. Serological tests are also important, although specificity is compromised by cross-reactions with other pig helminth parasites, especially in direct antibody ELISA tests. An ELISA developed to detect circulating antigen is reported to be of value in screening pigs for epidemiological purposes.*

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OR

Criteria 5: The *disease* or *infection* is an *emerging disease* with evidence of zoonotic properties, rapid spread, or significant morbidity or mortality and a *case* definition is available to clearly identify *cases* and allow them to be distinguished from other *diseases* or *infections*.

Ad hoc Group comment: *Porcine cysticercosis is overall not emergent, or rapid spreading. However, with the introduction of pigs in rural farming communities by donor agencies in most countries in Africa and the short reproductive cycle of pigs, human infection with* T. solium *should be considered as emergent and is spreading rapidly in this region. Public health efforts for its control in pig and human populations are active in many countries (e.g. Peru, Mexico, West and Southeast African countries).*

…/ Annexes

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Annex XXXIII (contd)

Annex 1

MEETING OF THE OIE ELECTRONIC *AD HOC* GROUP ON THE LISTING OF *TAENIA SOLIUM*

December 2012–January 2013

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List of participants

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Annex XXXIV

Original: English

September 2012

REPORT OF THE MEETING OF THE
OIE AD HOC GROUP ON VETERINARY LEGISLATION

Paris (France), 25–27 September 2012

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1. Welcome, adoption of the agenda and introductory remarks

Dr David Sherman, Chair of the *ad hoc* Group on Veterinary Legislation (*ad hoc* Group), opened the meeting and welcomed the participants, noting that, thanks to the great work of the *ad hoc* Group, the new chapter on veterinary legislation in the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) was successfully adopted at the 80th OIE General Session in May 2012. The agenda was discussed and approved. A list of participants and the adopted agenda are given at Annexes I and II.

2. Meeting with the OIE Director General

The *ad hoc* Group met Dr Bernard Vallat, the Director General of the OIE, on the first day of the *ad hoc* Group meeting. Dr Sherman outlined the expected work of the *ad hoc* Group including reviewing European Union (EU) and Food and Agriculture Organization of the United Nations (FAO) comments on the *Terrestrial Code* Chapter 3.4., reviewing the questionnaire for the Veterinary Legislation Support Programme (VLSP) with a view to align it with Chapter 3.4. and to make it more user-friendly; and discussing the possibility to have a feedback session on VLSP. Dr Sherman noted that in reviewing the Member comments on Chapter 3.4. some comments were identified as useful for improving the clarity of the text in the chapter while there were many comments which were already addressed in some way by the current text. Dr Sherman pointed out that the *ad hoc* Group had identified two important terms, i.e. 'veterinary legislation' and 'veterinary medicine/science', which should be defined with a careful review in the context of the *Terrestrial Code*. Dr Sherman invited the OIE to refer this point to the Terrestrial Animal Health Standards Commission (TAHSC).

Dr Vallat thanked the *ad hoc* Group for their great contribution which had enabled the important step of the OIE in relation to its continuous effort to provide technical support to the OIE Member Countries for strengthening their Veterinary Services.

Dr Vallat also noted that it was timely to seek the possibility of organising a feedback session considering the progress of VLSP, which had been made to date. In response to Dr Sherman's suggestion, Dr Vallat undertook to refer the two definitions to TAHSC.

Dr Vallat noted that the OIE's capacity building activities in relation to veterinary legislation attracted the favourable attention of donors, especially in the African region and he promised to continue the effort to secure necessary resources to implement activities under the framework of the OIE PVS Pathway.

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Dr Ahmed El-Idrissi pointed out that reviewing the *Terrestrial Code* Chapter 3.4. and addressing Member comments requires expertise of both veterinary field and legal field. He also mentioned that close coordination with other international standards such as standards of Codex Alimentarius Commission is of great importance. In response Dr Vallat, while recognising the importance of legally appropriate uses of terms, stressed that change in the text should be done without changing the technical content. As regards the coordination with other international standard setting bodies, Dr Vallat agreed to maintain close collaboration with those organisations. He stressed that veterinary legislation design needs the permanent collaboration between lawyers and veterinarians.

3. Update on other *ad hoc* groups (veterinary education, evaluation of Veterinary Services and evaluation of Aquatic Animal Health Services)

Dr Masatsugu Okita (OIE International Trade Department) updated the *ad hoc* Group on the developments made by three *ad hoc* groups in relation to Veterinary Services, i.e. *ad hoc* groups on evaluation of Veterinary Services; on veterinary education and on evaluation of Aquatic Animal Health Services. He highlighted the major outcomes of each *ad hoc* Group.

The *ad hoc* Group noted that in the report of the *ad hoc* Group on Veterinary Education, more specifically in the draft model core curriculum guidelines, that for the core course 'clinical and diagnostic skills' the specific day 1 competencies associated with that course were incorrectly and inadequately listed. The only specific day 1 competency identified was "veterinary products" which seemed largely unrelated. The more appropriate competencies impacted by clinical and diagnostic skills would be, at the least, transboundary animal diseases, zoonoses, emerging and re-emerging diseases, and food hygiene. The *ad hoc* Group suggested the OIE to refer this point to the *ad hoc* Group on Veterinary Education.

4. Review of Member Country comments on Chapters 3.2. and 3.4. including the interventions made during the 80th General Session in May 2012

The *ad hoc* Group noted that the TAHSC had referred comments from the EU, FAO and *ad hoc* Group on veterinary education in relation to veterinary legislation in Chapters 3.2. and EU and FAO in Chapter 3.4.

Veterinary legislation (Chapter 3.4.)

In response to the general comments pointing out the need for Veterinary Authorities to set up a coordination mechanism with other national authorities and to give due consideration to the division of tasks between central and decentralised level, the *ad hoc* Group agreed with the comment and noted that Article 3.4.5. has already addressed this comment.

The comment requesting a clear mention in the introduction that veterinary legislation should be implemented by other competent authorities than the veterinary authority was not accepted because it was clearly covered by the second paragraph of Article 3.4.1.

The *ad hoc* Group carefully reviewed comments on Article 3.4.2. (definitions). The *ad hoc* Group was of the view that the chapter needs clear definitions of certain terminologies so that all users can interpret the terms used in this chapter precisely as originally defined. Nevertheless, the *ad hoc* Group agreed with a Member comment to delete the definitions of 'legal certainty' and 'Quality of legislation' and include the concept of those terms into point 5 of Article 3.4.3.

The *ad hoc* Group did not accept the comment to delete the definition of 'primary legislation' and 'secondary legislation' on the basis that the executive body can approve primary legislation in certain cases, because while the executive body may retain the authority to approve or reject primary legislation, it is the legislative body which creates that primary legislation. The *ad hoc* Group considered it important to retain the definitions of primary and secondary legislation as they are fundamental concepts for the development of effective veterinary legislation.

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The *ad hoc* Group noted that the Glossary to the *Terrestrial Code* has a definition of 'veterinary legislation' while Chapter 3.4. has its own slightly different definition of 'veterinary legislation'. The *ad hoc* Group decided to refer this point to the TAHSC and invite them to review these two definitions and provide guidance.

The comment on Article 3.4.3. suggesting to include several points for legal drafting in the general principles was not accepted on the basis that those points raised by the comment had been addressed in other articles already.

The *ad hoc* Group noted the comment pointing out that sub-point c) of Article 3.4.4. is not correct. The text was revised for improved clarity.

The comment on sub-point f) of Article 3.4.4. was not accepted because the term sanction in English has both positive and negative meanings, both of which should be retained.

The comment on sub-point g) of Article 3.4.4. was not accepted, either, because the *ad hoc* Group considered that the current text sufficiently addressed this comment.

The comment on Article 3.4.5. suggesting to add an additional stipulation that one national authority (normally central authorities) should hold the ultimate responsibility to maintain the animal health status was not accepted because there are some countries whose constitutions require a decentralised approach in maintaining animal health status. The other two comments on this article were accepted and the text was revised as appropriate.

In point 1 of Article 3.4.6., the text was modified based on part of the EU's comments. The *ad hoc* Group discussed the definition of veterinary medicine/science extensively and invites the TAHSC to consider the need to define this terminology.

The comment on Article 3.4.10. suggesting to list specific issues for OIE animal welfare standards was noted and 'Section 7' was added referring to that part of the *Terrestrial Code*.

The comment on Article 3.4.11. was not accepted because the *ad hoc* Group felt this comment has been sufficiently addressed by the current text.

The comment on Article 3.4.12. suggesting to make a reference to the need to coordinate with food safety legislation and authorities was not accepted because this has been addressed by referring to Chapter 6.1. In response to the suggestion to introduce more open formulation in point 2 b), the *ad hoc* Group deleted 'on the basis of veterinary expertise'.

The proposed revision of the chapter is attached as Annex III.

Evaluation of Veterinary Services (Chapter 3.2.)

The *ad hoc* Group reviewed comments received from FAO, which suggested that Article 3.2.7. be moved to or combine with relevant Articles in Chapter 3.4.

The *ad hoc* Group noted that the overall objective of Chapter 3.2. is to provide guidance to Member Countries which would like to evaluate the Veterinary Services of another country while Chapter 3.4. is intended for Member Countries wishing to establish or modernise their veterinary legislation. They also noted that the styles of the chapters differed greatly. Hence, the *ad hoc* Group was of the view that removing the text regarding veterinary legislation from Chapter 3.2. could undermine the purpose of that chapter. Moreover, the *ad hoc* Group had a concern that making reference to Chapter 3.4. could lead to unnecessary trade implications for this chapter.

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While in favour of retaining Article 3.2.7., the *ad hoc* Group noted that the scope of the Article 3.2.7. should be aligned with Chapter 3.4. However, it is recommended that the entire chapter be reviewed rather than revising only Article 3.2.7. in a piecemeal manner. Such a systemic revision of all articles should be done by experts of evaluation of Veterinary Services so as not to undermine the integrity and narrative style of the current chapter. Hence, the *ad hoc* Group decided to seek TAHSC advice on how to address this inconsistency.

5. Revision of the questionnaire to ensure congruency with the text of Chapter 3.4.

The *ad hoc* Group reviewed the questionnaire in Annex 1 of the Manual for Experts of the VLSP with a view to align it with the text of Chapter 3.4. and to make it more user-friendly. The *ad hoc* Group considered it appropriate that the revised questionnaire would be uploaded on the OIE website for information of Member Countries that would like to apply for VLSP.

Dr Martial Petitclerc outlined the background and the intended use of the questionnaire. He explained that the use of the questionnaire was important even when countries could not complete all questions in it because the answers (and unanswered questions) could indicate the legislative weakness existing in the Veterinary Service of the country and the expert could analyse the situation beforehand and fill the gap during the VLSP mission. He noted that use of the questionnaire could be considered flexibly by each VLSP expert depending on the situation of the country and the questionnaire could be improved but stressed that the questionnaire needs to be simple and to use closed questions in order to avoid over-interpretation.

The *ad hoc* Group reviewed each question in the questionnaire closely together with the explanatory notes, bearing in mind the intended use Dr Petitclerc outlined and, on the other hand consistency with Chapter 3.4. of the *Terrestrial Code* and improved clarity and user-friendliness.

In discussing the questionnaire, the *ad hoc* Group identified the need for expertise in the use of legal terms when reviewing this type of legal document. The *ad hoc* Group proposed that the OIE consider inviting a bilingual legal expert to become a member of this *ad hoc* Group.

Q1 – Information on the State's political, administrative and legal organisation

The *ad hoc* Group felt that open-ended questions could be easier for users than filling in the pre-determined table when describing the administrative divisions and their legal responsibilities of the country as well as the court system. In addition some changes in use of legal terms were made for improved clarity.

Q2 – Hierarchy of the texts

The term 'text' was replaced with 'legal instrument' to avoid confusion. This change was applied throughout the questionnaire, as appropriate.

The *ad hoc* Group noted that introductory text was titled 'Guidelines' in several questions but since the Veterinary legislation guidelines have been superseded by Chapter 3.4. this reference was deleted.

Q3 – Legal documentation – basis, creation and management

The introductory part of the explanatory note was discussed. As this text was extracted from the guidelines and not consistent with Chapter 3.4. of the *Terrestrial Code*, the *ad hoc* Group considered that this introductory text could lead to confusion. Moreover, the *ad hoc* Group felt that the text was too prescriptive and therefore would be off-putting for users. Thus, the Group decided to delete this text.

In addition, the *ad hoc* Group decided to change the order of the questions for better logical flow.

Q4 – Creation of texts – methodology – legal drafting (legistics)

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In this question, the *ad hoc* Group considered it appropriate to introduce an open-ended question for describing the procedure of formulating both primary legislation and secondary legislation in the country before moving to the specific closed questions. It was noted that an explanatory note should be developed for these two open-ended questions to ensure the expected information can be obtained. The *ad hoc* Group reviewed the closed questions and decided to delete the second question as this could be covered by the two open-ended questions.

The 5th question (new 6th question) was amended to indicate explicitly that this question is intended for the evaluation during drafting.

The 6th question (new 7th question) was replaced with a request for template because the open-ended questions could cover the original question.

Further amendments were made to Q4 for improved clarity.

Q5 – Definition of the veterinary domain and the division of responsibilities

The *ad hoc* Group conducted a cross-check with Chapter 3.4. of the *Terrestrial Code* for congruency. Though recognising discrepancy between this question and Chapter 3.4., the *ad hoc* Group noted that the intention of this question was to identify the legislation and controlling bodies in each subject in the entire veterinary domain and thus, this question does not necessarily have to be fully consistent with Chapter 3.4. The *ad hoc* Group amended and added some secondary subjects which were deemed necessary. In addition, the explanatory note was revised for improved clarity.

Q6 – Inspectors

[no change]

Q7 – Financial framework

While noting that this question was not directly relevant for veterinary legislation, the *ad hoc* Group considered it useful information and decided to retain it. It was decided to use an open-ended style in order to indicate the intention of the question more explicitly.

The *ad hoc* Group considered the revised questionnaire might need further adjustment to ensure that it is workable in actual field circumstances. The *ad hoc* Group recommended that the OIE consider field trials of the questionnaire in forthcoming VSLP missions, so that the *ad hoc* Group can make fine tuning based on the results of such field trials at its next meeting. The revised questionnaire is attached in Annex IV.

Although not included in the expert manual of VLSP, so-called 'Part 2 of the questionnaire (technical questionnaire)', it was recommended by the *ad hoc* Group that it should be included among the materials which need to be completed by the country prior to the identification mission (Annex V).

6. Update on the state of play with the OIE Veterinary Legislation Support Programme including planning of a feedback session in 2013

Update on the state of play with the OIE Veterinary Legislation Support Programme

Dr François Caya, Head of OIE Regional Activity Department, updated the *ad hoc* Group on the OIE PVS Pathway including VLSP. He explained states of play with all three types of PVS Pathway mission (PVS evaluation, PVS Gap Analysis and VLSP) and related activities. With respect to VLSP, he outlined the developments made since the last *ad hoc* Group meeting. Dr Caya's presentation is attached in Annex VI.

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Annex XXXIV (contd)

Discussion on planning of a feedback session for VLSP and proposed dates of next meeting

The *ad hoc* Group noted that a feedback session for VLSP was proposed taking into account that approximately 30 VLSP identification missions had been conducted. The *ad hoc* Group discussed the possible programme of the session and recommended that the OIE consider including the following in topics in the feedback session:

- Feedback from VLSP experts: the *ad hoc* Group recommended the OIE send a questionnaire in order to collect experts' opinions on various aspects of the VLSP including technical content, procedures, quality of the Manual of VLSP, etc, prior to the feedback session and share the result with the experts.

- Impact of the identification mission (feedback from beneficiaries): the *ad hoc* Group noted that the impact of identification missions should be analysed and shared among the experts. It was recommended the OIE send a survey form to beneficiary countries to collect their self-evaluation of the impact of missions.

- Clarification for the intention of the questionnaire: after reviewing the questionnaire taking into consideration the original intention of this questionnaire, the *ad hoc* Group noted that it is important that experts of VLSP should fully understand the purpose and how to use this questionnaire before conducting a mission. The *ad hoc* Group recommended the OIE provide a targeted training on this during the feedback session.

The International Trade Department undertook to consider these recommendations for developing the programme of the feedback session.

Given that the number of VLSP experts is relatively limited and the *ad hoc* Group consists solely of VLSP experts, it was agreed, in principle, to hold the feedback session back to back with the next *ad hoc* Group meeting. The *ad hoc* Group noted that dates proposed were 1st half of April 2013.

It was proposed to hold the next meeting in the 1st half of April 2013 (dates to be confirmed).

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…/Annexes

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Annex XXXIV (contd)

Annex I

MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY LEGISLATION

Paris, 25–27 September 2012

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Annex II

MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY LEGISLATION

Paris, 25–27 September 2012

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Adopted agenda

Day 1 (Tuesday, 25 September 2012) 9:30-17:00

- Welcome, adoption of the agenda, and introductory remarks
- Discussion with the OIE Director General (25 September, 16:30)
- Update on other *ad hoc* groups (veterinary education, evaluation of Veterinary Services and evaluation of Aquatic Animal Health Services)
- Review of Member Country comments on Chapters 3.2. and 3.4. including the interventions made during the 80th General Session in May 2012

Day 2 (Wednesday, 26 September 2012) 9:00-17:00

- Revision of the questionnaire to ensure congruency with the text of Chapter 3.4.
- Update on the state of play with the OIE Veterinary Legislation Support Programme including planning of a feedback session in 2013

Day 3 (Thusday, 27 September 2012) 9:00-17:00

- Review of the draft report
- Date of next meeting.

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Annex III

CHAPTER 3.4.

VETERINARY LEGISLATION

Article 3.4.1.

Introduction and objective

Good governance is a recognised global public good and is of critical importance to OIE Members. Legislation is a key element in achieving good governance.

Veterinary legislation should, at a minimum, provide a basis for *Competent Authorities* to meet their obligations as defined in the *Terrestrial Code* and the relevant recommendations of the Codex Alimentarius Commission. In addition, there is an obligation for World Trade Organization (WTO) Members under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to notify the WTO of changes in sanitary measures, including changes in legislation that affect trade, and provide relevant information.

For the purposes of the *Terrestrial Code*, veterinary legislation comprises all legal instruments necessary for the governance of the veterinary domain.

The objective of this chapter is to provide advice and assistance to OIE Members when formulating or modernising veterinary legislation so as to comply with OIE standards, thus ensuring good governance of the entire veterinary domain.

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

Hierarchy of legislation: means the ranking of the legal instruments as prescribed under the fundamental law (e.g. the constitution) of a country. Respect for the hierarchy means that each legal instrument must comply with higher order legal instruments.

~~**Legal certainty:** means the situation in which the legislation is clear, coherent, stable and transparent, and protects citizens against adverse side effects of legal instruments.~~

Legal instrument: means the legally binding rule that is issued by a body with the required legal authority to issue the instrument.

Primary legislation: means the legal instruments issued by the legislative body of a Member.

~~**Quality of legislation:** means the technical relevance, acceptability to society, sustainability in technical, financial and administrative terms and provision of a basis for effective implementation of laws.~~

Secondary legislation: means the legal instruments issued by the executive body of a Member under the authority of primary legislation.

Stakeholder: means a person, group, or organisation that can affect or be affected by the impacts of veterinary legislation.

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Veterinary domain: means all the activities that are directly or indirectly related to *animals*, their products and by-products, which help to protect, maintain and improve the health and welfare of humans, including by means of the protection of animal health and welfare, and food safety.

Veterinary legislation: means the collection of specific legal instruments (primary and secondary legislation) required for the governance of the veterinary domain.

Article 3.4.3.

General principles

1) Respect for the hierarchy of legislation

Veterinary legislation should scrupulously respect the hierarchy between primary legislation and secondary legislation.

2) Legal basis

Competent Authorities should have available the primary legislation and secondary legislation necessary to carry out their activities at all administrative and geographic levels.

Veterinary legislation should be consistent with national and international law, as appropriate, including civil, penal and administrative laws.

3) Transparency

Veterinary legislation should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate.

Competent Authorities should ensure communication of veterinary legislation and related documentation to stakeholders.

4) Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving *Competent Authorities* and legal experts to ensure that the resulting legislation is scientifically, technically and legally sound.

To facilitate implementation of the veterinary legislation, *Competent Authorities* should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.

5) Quality of legislation and legal certainty

Veterinary legislation should be clear, coherent, stable and transparent and protect citizens against unintended adverse side effects of legal instruments. It should be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

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Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

a) be drafted in a manner that establishes clear rights, responsibilities and obligations (i.e. 'normative');

b) be unambiguous, with clear and consistent syntax and vocabulary;

c) be precise and accurate and consistent in the repeated use of the terminology ~~even if this results in repetition and a cumbersome style~~;

d) contain no definitions that create any conflict or ambiguity;

e) include a clear statement of scope and objectives;

f) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and

g) make provision for the financing needed for the execution of all activities of *Competent Authorities*; the financing should be ensured in accordance with the national funding system.

Article 3.4.5.

Competent Authorities

Competent Authorities should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly and coherently to address animal health, ~~and~~ public health and animal welfare emergencies effectively.

Veterinary legislation should provide for a chain of command that is as effective as possible (i.e. short, with all responsibilities clearly defined). For this purpose, the responsibilities and powers of *Competent Authorities*, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one *Competent Authority* is involved such as in relation to environmental, food safety or other public health matters a reliable system of coordination and cooperation should be in place.

Competent Authorities should appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the veterinary legislation, respecting the principles of independence and impartiality prescribed in Article 3.1.2.

1) Necessary powers of the Competent Authority

The veterinary legislation should also ensure that:

a) officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force;

b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith;

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c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality, as appropriate; and

d) at least the following powers are available through the primary legislation:

i) access to premises and vehicles for carrying out inspections;

ii) access to documents;

iii) taking samples;

iv) retention (setting aside) of *animals* and goods, pending a decision on final disposition;

v) seizure of *animals*, products and food of animal origin;

vi) suspension of one or more activities of an inspected establishment;

vii) temporary, partial or complete closure of inspected establishments; and

viii) suspension or withdrawal of authorisations or approvals.

These essential powers must be identified as they can result in actions that may conflict with individual rights ascribed in fundamental laws.

2) Delegation of powers by the Competent Authority

The veterinary legislation should provide the possibility for *Competent Authorities* to delegate specific tasks related to official activities. The specific tasks delegated, the body(ies) to which the tasks are delegated and the conditions of supervision by the *Competent Authority* should be defined.

For this purpose, the veterinary legislation should:

a) define the field of activities and the specific tasks covered by the delegation;

b) provide for the control, supervision and, when appropriate, financing of the delegation;

c) define the procedures for making delegation;

d) define the competencies to be held by persons receiving delegation; and

e) define the conditions of withdrawals of delegations.

Article 3.4.6.

Veterinarians and veterinary para-professionals

1) Veterinary medicine/science

In order to ensure quality in the conduct of veterinary medicine/science, the veterinary legislation should ~~provide a definition of veterinary medicine/science sufficient to address the following~~;

a) define the prerogatives of *veterinarians* and of the various categories of *veterinary para-professionals* that are recognised by the Member Country;

b) define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary para-professionals*;

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c) prescribe the conditions for recognition of the qualifications for *veterinarians* and *veterinary para-professionals*;

d) define the conditions to perform the activities of veterinary medicine/science; and

e) identify the exceptional situations, such as epizootics, under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2) The control of veterinarians and veterinary para-professionals

Veterinary legislation should provide a basis for regulation of *veterinarians* and *veterinary para-professionals* in the public interest. To that end, the legislation should:

a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;

b) describe the various categories of *veterinary para-professionals* recognised by the Member Country according to its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;

c) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to *veterinarians* and veterinary para-professionals;

d) provide for the possibility of delegation of powers to a professional organisation such as a *veterinary statutory body*; and

e) where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation.

Article 3.4.7.

Laboratories in the veterinary domain

1) Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;

b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and

c) *laboratories* recognised by the *Competent Authority* to conduct analyses required under the legislation e.g. for the purposes of quality control.

The veterinary legislation should define the conditions for the classification, approval, operations and supervision of *laboratories* at each level.

2) Reagents

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) procedures for authorising reagents that are used to perform official analyses;

b) quality assurance by manufacturers of reagents used in official analyses; and

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Annex III (contd)

c) surveillance of marketing of reagents, where these can affect the quality of analyses required by the veterinary legislation.

Article 3.4.8.

Health provisions relating to animal production

1) Identification and traceability

Veterinary legislation should provide a basis for actions to address all the elements in Article 4.2.3., point 6.

2) Animal markets and other gatherings

Veterinary legislation should address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

a) registration of animal markets and other animal gatherings;

b) health measures to prevent *disease* transmission, including procedures for cleaning and *disinfection*, and *animal welfare* measures; and

c) provision for veterinary checks.

3) Animal reproduction

Veterinary legislation should provide a basis for actions to address the health regulation of animal reproduction as appropriate. Health regulations may be implemented at the level of *animals*, genetic material, establishments or operators.

4) Animal feed

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) standards for the production, composition and quality control of animal feed;

b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and

c) recall from the market of any product likely to present a *hazard* to human health or animal health.

5) Animal by-products

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) definition of the animal by-products subject to the legislation;

b) rules for collection, processing, use and disposal of animal by-products;

c) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and

d) rules to be followed by animal owners.

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Annex III (contd)

6) Disinfection

Veterinary legislation should provide a basis for actions to address the regulation and use of products and methods of *disinfection* relating to the prevention and control of *animal diseases*.

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for the *Competent Authority* to manage *diseases* of importance to the country and to list those *diseases*, guided by the recommendations in Chapters 1.1. and 1.2.

1) Surveillance

Veterinary legislation should provide a basis for the collection, transmission and utilisation of epidemiological data relevant to *diseases* listed by the *Competent Authority*.

2) Disease prevention and control

a) Veterinary legislation should include general animal health measures applicable to all *diseases* and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular *diseases* listed in the country.

b) The legislation should also provide a basis for contingency plans to include the following for use in *disease* responses:

i) administrative and logistic organisation;

ii) exceptional powers of the *Competent Authority*; and

iii) special and temporary measures to address all identified *risks* to human or animal health.

c) Veterinary legislation should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of *killing* or *slaughtering* of *animals* and seizure or destruction of carcasses, *meat*, animal feed or other things.

3) Emerging diseases

Veterinary legislation should provide for measures to investigate and respond to *emerging diseases*.

Article 3.4.10.

Animal welfare

1) General provisions

Veterinary legislation should provide a basis for actions to address the *animal welfare* related requirements in Section 7 of the*Terrestrial Code*.

To this end, the legislation should contain, as a minimum, a legal definition of cruelty as an offence, and provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers.

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Annex III (contd)

2) Stray dogs and other free-roaming animals

Veterinary legislation should provide a basis for actions to address the requirements in Chapter 7.7. and, as appropriate, prohibition of the abandonment of *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

Article 3.4.11.

Veterinary medicines and biologicals

Veterinary legislation should provide a basis for assuring the quality of veterinary medicines and biologicals and minimising the *risk* to human, animal and environmental health associated with their use.

1) General measures

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) definition of veterinary medicines and biologicals, including any specific exclusions; and

b) regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary medicines and biologicals.

2) Raw materials for use in veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) quality standards for raw materials used in the manufacture or composition of veterinary medicines and biologicals and arrangements for checking quality;

b) establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and

c) requirements for substances in veterinary medicines and biologicals that may, through their effects, interfere with the conduct of veterinary checks.

3) Authorisation of veterinary medicines and biologicals

a) Veterinary legislation should ensure that only authorised veterinary medicines and biologicals may be placed on the market.

b) Special provisions should be made for:

i) medicated feed;

ii) products prepared by authorised *veterinarians* or authorised pharmacists; and

iii) emergencies and temporary situations.

c) Veterinary legislation should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.

d) In defining the procedures for seeking and granting authorisations, the legislation should:

i) describe the role of the relevant *Competent Authorities*~~y~~; and

ii) establish rules providing for the transparency in decision making.

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Annex XXXIV (contd)

Annex III (contd)

e) Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

4) Quality of veterinary medicines and biologicals

Veterinary legislation should address the following elements:

a) the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer;

b) conditions for the conduct of trials;

c) qualifications of experts involved in trials; and

d) surveillance for adverse effects arising from the use of veterinary medicines and biologicals.

5) Establishments producing, storing and wholesaling veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the following elements:

a) registration or authorisation of all operators manufacturing importing, storing, processing, wholesaling or otherwise distributing veterinary medicines and biologicals or raw materials for use in making veterinary medicines and biologicals;

b) definition of the responsibilities of operators;

c) good manufacturing practices as appropriate;

d) reporting on adverse effects to the *Competent Authority*; and

e) mechanisms for traceability and recall.

6) Retailing, use and traceability of veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the following elements:

a) control over the distribution of veterinary medicines and biologicals and arrangements for traceability, recall and conditions of use;

b) establishment of rules for the prescription and provision of veterinary medicines and biologicals to end users;

c) restriction to authorised professionals and, as appropriate, authorized veterinary paraprofessionals of commerce in veterinary medicines and biologicals that are subject to prescription;

d) the supervision by an authorised professional of organisations approved for holding and use of veterinary medicines and biologicals;

e) the regulation of advertising claims and other marketing and promotional activities; and

f) reporting on adverse effects to the *Competent Authority*.

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Annex XXXIV (contd)

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Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards. The role of the *Veterinary Services* in food safety is described in Chapter 6.1.

1) General provisions

Veterinary legislation should provide a basis for actions to address the following elements:

a) controls over all stages of the production, processing and distribution of food of animal origin;

b) recording all significant animal and public health events that occur during primary production;

c) giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;

d) inspection for compliance with food standards, where this is relevant to health or safety;

e) inspection of premises;

f) prohibition of the marketing of products not fit for human consumption; and

g) provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2) Products of animal origin intended for human consumption

Veterinary legislation should provide a basis for actions to address the following elements:

a) arrangements for inspection and audit;

b) the conduct of inspection and audit ~~on the basis of veterinary expertise~~;

c) health standards; and

d) the application of health identification marks that are visible to the intermediary or final user.

The *Competent Authority* should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

3) Operators responsible for premises and establishments pertaining to the food chain

Veterinary legislation should provide a basis for actions to address the following elements as appropriate:

a) registration of premises and establishments by the *Competent Authority*;

b) the use of risk-based management procedures; and

c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

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Annex XXXIV (contd)

Annex III (contd)

Article 3.4.13.

Import and export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements relating to import and export procedures and veterinary certification referred to in Section 5 of the *Terrestrial Code.*

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ANNEX 1

QUESTIONNAIRE

This questionnaire is provided to help the experts to assess the general situation in the country and prepare a work programme in line with the OIE Member's expectations.

Please refer to the explanatory notes while completing the questionnaire.

Some questions may duplicate information contained in the PVS or other documents to which the experts have access. If you have already completed some sections you are simply requested to confirm the data previously provided.

If any more explanation is required, please contact the Mission Leader.

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Annex XXXIV (contd)

Annex IV (contd)

Q1 – Information on the State's political, administrative and legal organisation

1. Fundamental legal instrument (e.g. Constitution) in force and laws relating to decentralisation (Enclose or attach the legal instruments in force):

2. Describe the administrative divisions of your country and their legal responsibilities from the central state down to the most local adminstrative division:

   Comments:

3. Describe the court system in your country (e.g. civil, penal, administrative). Identify which courts might be involved veterinary domain matters.

   Comments:

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Q2 – Hierarchy of the legal instruments

1 Legal instruments relating to the central State:

(1) Level of legal instruments	(2) Title	(3) Type	(4) Issuing authority	(5) Source of law or procedure for creation	(6) Cross-reference

2 Legal instruments relating to decentralised authorities:

(1) Level of legal instruments	(2) Title	(3) Type	(4) Issuing authority	(5) Source of law or procedure for creation	(6) Cross-reference

3 Legal instruments relating to authorities holding delegated powers (IF APPLICABLE):

(1) Level of legal instruments	(2) Title	(3) Type	(4) Issuing authority	(5) Source of law or procedure for creation	(6) Cross-reference

4 Additional comments:

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Annex XXXIV (contd) / Annex IV (contd)

Q3 – Legal documentation – basis, creation and management

1 Is there a general legal database or a database relating to veterinary legal instruments?

First and second level legislation: ..... Yes ..... ☐ ..... No ..... ☐

Infra-regulatory texts[1]: ..... Yes ..... ☐ ..... No ..... ☐

If you answered "Yes" at least once:

Computerised or manual database: ..... Computerised .. ☐ ..... Manual ..... ☐

Manager of the database: .....

Method of accessing the database:

For the Veterinary Services: .....

For the public: .....

Comments: .....

2 Is there a system of consolidation?

No ..... ☐ ..... Yes, computerised ..... ☐ ..... Yes, manual ..... ☐

Person in charge: .....

Comments: .....

3 Is veterinary legislation codified? Yes ☐ No ☐

Title of the Code: .....

Comments: .....

4 Does other legislation contain legal tools that are used by the VS?

Civil law: .....

Penal law: .....

Penal procedure: .....

Administrative law: .....

Environment: .....

Consumer protection: .....

Customs and finance: .....

Comments: .....

5 Legal publication

Procedures for legal publication: .....

Title of the official publication: .....

Are the Veterinary Services subscribers? ..... Yes ..... ☐ ..... No ..... ☐

Is there a system of internal circulation? ..... Yes ..... ☐ ..... No ..... ☐

6 Are there rules for disseminating veterinary legislation other than by legal publication?

Within the Veterinary Services: ..... Yes ..... ☐ ..... No ..... ☐

To other administrations: ..... Yes ..... ☐ ..... No ..... ☐

To organised groups of stakeholders: ..... Yes ..... ☐ ..... No ..... ☐

To the public: ..... Yes ..... ☐ ..... No ..... ☐

[1] In addition to the legislation, information may be provided on the procedures for its implementation. The administration can disseminate its operating rules, for example by means of a bulletin or periodic digests. Such information is known as intra-regulatory texts.

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If you answered "Yes":

Reference document setting out the rules: .....

Method of dissemination: .....

Distribution lists: .....

Comments: .....

7 Rules for disseminating information that is subordinate and relevant to regulatory texts (infra-regulatory texts)?

Within the Veterinary Services: ..... Yes ..... ☐ ..... No ..... ☐

To other administrations: ..... Yes ..... ☐ ..... No ..... ☐

To organised groups of stakeholders: ..... Yes ..... ☐ ..... No ..... ☐

To the public: ..... Yes ..... ☐ ..... No ..... ☐

If you answered "Yes" at least once:

Reference document setting out the rules: .....

Method of dissemination: .....

Distribution lists: .....

Rules regarding confidentiality: .....

Comments: .....

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Annex XXXIV (contd) / Annex IV (contd)

Q4 – Creation of legal instruments – methodology – legal drafting (legistics)

1 What is the procedure for creating and approving the primary legislation from inception to final enactment in your country? Identify all steps and the administrative divisions involved and the amount of time from inception to passage.

2 What is the procedure for creating and approving the secondary legislation (regulations) in your country? Identify all steps and the administrative divisions involved and the amount of time from inception to passage.

3 Are there formal rules for legal drafting? Yes ☐ No ☐

If "Yes", please indicate the reference:.....

Comments:.....

4 For the creation or updating of veterinary legislation:

Are the legal instruments always an initiative of the Veterinary Services? .. Yes .... ☐ .....No.....☐

Are legal experts involved at the design stage?..... Yes .... ☐ .....No.....☐

Do veterinarians/ technicians systematically work with legal experts?..... Yes .... ☐ .....No.....☐

Comments:.....

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5 Is consultation undertaken during legal drafting?

With the public? ..... Yes .... ☐ .....No..... ☐
Is there a formal procedure? ..... Yes .... ☐ .....No..... ☐
With professionals? ..... Yes .... ☐ .....No..... ☐
Is there a formal procedure? ..... Yes .... ☐ .....No..... ☐
With other administrations? ..... Yes .... ☐ .....No..... ☐
Is there a formal procedure? ..... Yes .... ☐ .....No..... ☐

Comments: .....

6 Is there a formal evaluation of the applicability and impact of the legal instruments as part of their creation (e.g. regulatory impact assessment)?

For primary legislation? Never ☐ . Sometimes.... ☐ Always ..... ☐
For secondary legislation? Never ☐ . Sometimes.... ☐ Always ..... ☐
For infra-regulatory texts? Never ☐ . Sometimes.... ☐ Always ..... ☐

Comments: .....

7 What do these evaluations usually take into account?

If a template exists for these evaluations, please attach it.

Comments: .....

8 Are performance indicators developed in parallel with the legal instruments to monitor the success of the legal provisions when they are implemented? Yes ☐ No ☐

Comments: .....

9 Is there usually a timetable for implementation? Yes ☐ No ☐

Comments: .....

10 When primary legislation is drafted, is the relevant secondary legislation drafted at the same time?

Comments: .....

UNOFFICIAL VERSION

Annex XXXIV (contd) / Annex IV (contd)

Q5 – Definition of the veterinary domain and distribution of responsibilities

1 Is the 'veterinary domain' defined for official purposes? **Yes ☐ No ☐**

1.1. If you answered "Yes", please state the definition and give the reference for the legal instrument:

2 For each domain, indicate the distribution of responsibilities:

Domain			Legislation		Control		Ref. comments (8)
N°	Primary (2)	Secondary (3)	4	Authority responsible for preparation (5)	1st level of control (6)	2nd level of control (7)	
1a	Veterinary profession	Private	☐				
1b		Public	☐				
1c		Initial training	☐				
2a	Veterinary para-professionals	Private	☐				
2b		Public	☐				
2c		Initial training	☐				
3a	Laboratories	Animal health	☐				
3b		Food safety	☐				
4a	Livestock production	Identification of animals	☐				
4b		Genetics – artificial breeding	☐				
4c		Feed	☐				
4d		Environmental impact	☐				
4e		Animal markets and other gathering	☐				
4f		Animal by-products	☐				
4g		Disinfection	☐				
5	Protection of animals	Welfare	☐				
6	Protection of species	CITES	☐				

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Domain			Legislation		Control		Ref. comments (8)
N°	Primary (2)	Secondary (3)	4	Authority responsible for preparation (5)	1st level of control (6)	2nd level of control (7)	
7a	Animal health	Surveillance	☐				
7b		Disease prevention control	☐				
7b		Emerging diseases	☐				
7c		Wildlife diseases	☐				
8a	Food safety	Primary production: milk	☐				
8b		Primary production: meat	☐				
8c		Primary production: poultry meat	☐				
8d		Primary production: eggs	☐				
8e		Primary production: fisheries	☐				
8f		Processing industry	☐				
8g		Transport	☐				
8h		Retail	☐				
8i		Restaurant	☐				
9a	Veterinary products	Production	☐				
9b		Licensing/registration	☐				
9c		Retail	☐				
9d		Residue control	☐				
10a	Export certification	Animals	☐				
10b		Animal products	☐				
11a	Import controls	Animals	☐				
11b		Animal products	☐				
11c		Pharmaceuticals	☐				

UNOFFICIAL VERSION

Annex XXXIV (contd) / Annex IV (contd)

Q6 – Inspectors

	(1) Objectives	(2)	Legal basis			(6) Comments
			(3) Primary legislation	(4) Secondary legislation	(5) Infra-regulatory texts	
1	Inspectors have a defined field of intervention	☐				
2	Inspectors have a defined intervention territory	☐				
3	Inspectors' regulatory powers are defined	☐				
4	There is a penal procedure for exercising regulatory powers	☐				
5	Inspector's administrative and enforcement powers are defined	☐				
6	There is a penal procedure for exercising administrative and enforcement powers	☐				
Inspectors have the right or power of:						
7	Access to premises and vehicles	☐				
8	Requiring access to any document for inspection purposes	☐				
9	Taking samples	☐				
10	Detention of items	☐				
11	Seizure of items	☐				
12	Injunction	☐				
13	Closure	☐				
14	Calling in the police force	☐				
15	Inspectors are protected in the performance of their duties	☐				
16	Stakeholders have the right of appeal against administrative decisions	☐				

UNOFFICIAL VERSION

Q7 – Financial framework

1 Central Veterinary Services:

What proportion of the budget for Central Veterinary Service comes from each of the following sources:

Annual State budget ..... %

Fees paid to the government for services ..... %

Other sources of income (e.g. international donors, industry) ..... %

Comments: .....

2 Territorial Veterinary Services:

What proportion of the budget for Territorial Veterinary Service comes from each of the following sources?

Annual State budget ..... %

Fees paid to the government for services ..... %

Territorial budget ..... %

Other sources of income ..... %

Comments: .....

3 Are fees paid by users for any of the following services?:

Action		% retained by the Vet. Services
Inspection of animals, meat or other products	☐	
Processing applications e.g. for approval, authorisation, licensing	☐	
Export certification	☐	
Import controls	☐	
Diagnostic testing	☐	
Sale of other services or products	☐	

4 Numerical data:

Criterion	Absolute value	%
National GDP		100
Livestock sector as a percentage of national GDP		
Agri-food sector as a percentage of national GDP		
State budget *		100
VS budget as a percentage of the State budget *		

* including total payroll

UNOFFICIAL VERSION

Annex XXXIV (contd) / Annex IV (contd)

ANNEX 2

QUESTIONNAIRE–ADVISORY NOTES

The identification mission forms part of the support programme for veterinary legislation and is conducted at the request of the OIE Member. Its aim is to determine the situation with regard to legislation, to identify limiting factors and possible avenues for improvement.

The preparatory questionnaire enables the experts to carry out an evaluation, focusing on the key points, with a view to proposing a work programme appropriate to the Member's context and needs.

The questionnaire is a little complicated as the terminology is specialised and the answers may be complex and difficult to summarise. However, the aim is to obtain an overall impression rather than precise details. The respondent should not spend too much time completing the questionnaire as the experts will add information where necessary during their mission.

The explanatory notes, which indicate the purpose of each question, are provided to help the respondent prepare the answers. The notes cover the whole questionnaire and present the following:

For the tables:

- objectives and explanation

- in some cases, sample answers are given to help the respondent.

The questionnaire is in Word™ format. Using it directly in this format may change the page layout but this is of no importance.

UNOFFICIAL VERSION

Q1 – Information on the State's political, administrative and legal organisation

A Purpose

The aim of this questionnaire is to obtain a description of the general organisation of the State's veterinary legislation and to identify the distribution of powers of the executive body or bodies and the overall legal organisation.

B Questionnaire

1 Fundamental legal instrument (e.g. Constitution) currently in force and laws relating to decentralisation (Attach copies of the current legal texts):

The aim is to list and if possible provide a copy of the legal instruments currently in force so as to identify the distribution of powers between the central State and decentralised authorities. An examination of the Constitution will enable the experts to evaluate the distribution of powers and the respective domains of the laws and the regulations.

2 Describe the administrative divisions of your country and their legal responsibilities (Legal responsibility limited to veterinary domain)**:**

3 Describe the court system in your country (e.g. civil, penal, administrative). Identify which courts might be involved veterinary domain matters.

The aim is to summarise the legal system. The respondent should indicate if the legal system is largely based on civil law, common law, religious law or customary law.

UNOFFICIAL VERSION

Annex XXXIV (contd) / Annex IV (contd)

Q2 – Hierarchy of the legal instruments

A Reference

Veterinary legislation should scrupulously respect the separation between primary legislation, represented by primary acts (laws), and the secondary legislation derived from regulations or rule books as laid down in the Constitution or other fundamental legal instruments of the OIE Member.

B Objectives

The aim is to identify the legal instruments used by the Veterinary Authority. Relevant information includes the name of the legal instruments and the authority responsible for preparing and enacting them. Where appropriate, the position of the legal instruments in the hierarchy and written rules of procedure, if these exist, should be mentioned. Informal rules of procedure can be described in an appendix.

C Questionnaire

1. Legal instruments relating to the central State: *example*

(1) Level of legal instrument	(2) Title	(3) Type	(4) Issuing authority	(5) Source of law or procedure for creation	(6) Cross-reference
1	Organic law	Legislative	Parliament	Articles x to y of the Constitution	
2	Law	Legislative	Parliament	Article z of the Constitution	
2b	Statutory order	Legislative	Government	Constitution – legislative empowerment	
3	Decree	Regulatory	Government	Circular/decree No. xx	
4	Ministerial order	Regulatory	Minister		
5	Directive	Administrative	Directorate-General and sub-directorates	Ministerial directive No. yy	

This table covers legal instruments issued at the central State level and applicable throughout the country.

UNOFFICIAL VERSION

1. Level of legal instrument: from the highest level, No. 1 (Constitution or equivalent), to the lowest level, n. Legal instruments should be in strict conformity with and authorised by legal instruments of higher levels. For example, a decree can modify another decree but not a law. Legal instruments may have the same rank but require different adoption procedures, such as laws and statutory orders or the various categories of decree.

2. Indicate the local name of the legal instrument.

3. Indicate the constitutional, legislative, regulatory or administrative type. Please note that the administrative instruments (directives, instructions, etc.) do not form part of the legislation should be identified here for information.

4. Indicate the authority responsible for adopting the final legal instrument.

5. Indicate the texts or articles on which the description of the level and the procedures for adoption are based.

6. As needed, a more detailed description may be annexed or appropriate references included in this column.

2. Legal instruments relating to decentralised authorities

This table deals with legal instruments relating to decentralised authorities, i.e. independent of the central State (although the latter may have the power of legal review).

Example:

(1) Level of legal instrument	(2) Title	(3) Type	(4) Issuing authority	(5) Source of law or procedure for creation	(6) Cross-reference
	Order	Regulatory	Head of the region	Decentralisation Law x, Article y	Legal instrument enclosed
	Order	Regulatory	Mayor	Code relating to districts, Article z	

The decentralised authority is an entity with its own competencies and powers, which it exercises autonomously without having to refer to the State or another authority. It is usually subject to legal review by the State or the competent jurisdictions.

UNOFFICIAL VERSION

Annex XXXIV (contd) / Annex IV (contd)

Indicate the legal instruments produced by the decentralised authorities (please refer to the explanations given in the previous section). The level is optional and, where appropriate, relates to legal instruments produced by the same authority. For example, a municipal order is independent of a decision of the President of the Regional Council, since they each act within their own field of competence.

Note: This table is mainly for information and detailed responses are not needed.

3. Legal instruments relating to authorities holding delegated powers

These are legal instruments issued locally by representatives of the State or persons holding relevant delegated powers (e.g. technical directors and heads of department). The authority holding the delegated power is a geographical or functional entity that is competent in place of the central authority. The authority holding the delegated power remains in a position of subordination.

Example:

(1) Level of legal instrument	(2) Title	(3) Type	(4) Issuing authority	(5) Source of law or procedure for creation	(6) Cross-reference
	Order	Regulatory	Governor	Decree No. xx, Article gg	
	Decision	Regulatory	Departmental Director of the Veterinary Services	Delegation order, etc.	

4. Additional comments

Please provide comments on the relationships between the legal instruments produced by the authorities and any other information relevant to the veterinary legislation or the implementation of animal and public health policies. For example, it may be the case that local authorities grant subsidies for the control of animal diseases in the locality. They do not have authority over animal health inspection but may have a considerable influence on health policy.

UNOFFICIAL VERSION

Q3 – Legal documentation – basis, creation and management

Explanations on the use of the questionnaire

1. Is there a general legal database or a database relating to veterinary legal instruments?

By "database", we mean a reliable source of information (manual or electronic) that may belong to the Veterinary Services or other governmental service, giving access to legal instruments in force that are relevant to the Veterinary Services.

In addition to the legislation, information may be provided on the procedures for its implementation. The administration can disseminate its operating rules, for example by means of a bulletin or periodic digests. Such information is known as infra-regulatory texts.

The requirement for confidentiality is a relevant consideration

First and second level legislation: ..... Yes ..... ☐ ..... No ..... ☐

Infra-regulatory texts:..... Yes ..... ☐ ..... No ..... ☐

If you answered "Yes" to one of these questions:

Computerised or manual database? ..... Computerised .. ☐ ..... Manual ..... ☐

Manager of the database:.....

Method of accessing the database:

By the Veterinary Services: .....

By the public: .....

Comments: .....

2. Is there a system of consolidation?

Consolidation means the integration into the legal instruments of all subsequent modifications, whatever their origin. This provides a clear picture of the current state of the law.

No ☐..... Yes, computerised..... ☐ ..... Yes, manual ☐

Comments: .....

3 Is veterinary legislation codified? Yes ☐ No ☐

''Codification" means the compilation in a single document of all or most of the primary legislation and the principal regulations (first levels of secondary or regulatory texts).

Codification differs from a collection of legal instruments in that it retains only the contents of the legal instruments.

Title of the Code: .....

Comments: .....

UNOFFICIAL VERSION

Annex XXXIV (contd) / Annex IV (contd)

4 Does other legislation contain legal tools that are used by the VS?

This refers to standard legal provisions, which are not specific to the Veterinary Services but which are used by them, explicitly or implicitly. For example, some breaches are covered by penal law and the veterinary legislation simply refers to it. Legal instruments on consumer protection may give the Veterinary Services competencies without giving the overall authority for consumer protection to the ministry responsible for the Veterinary Services (e.g. recording cases of fraud).

In a similar way the legal instruments relating to penal procedures often set the rules for recording breaches or defining the competencies of officials. Provisions for regulating the professions may be linked with legal instruments dealing with the control of private companies. The veterinary legislation may not necessarily govern these measures but a veterinary legal instrument may introduce the necessary modifications for the Veterinary Services to be able to carry out their missions.

Examples:

Civil law: *action to prevent the sale of sick animals* .....

Penal law: *the offence of preventing officials from carrying out their duty* .....

Penal procedure: *rules governing the recording of breaches* .....

Administrative law: *obligations relating to administrative appeals* .....

Environment: *legislation on protected species (e.g.CITES listed species)* .....

Consumer protection: *detection of fraud and falsification* .....

Customs and finance: *licensing of inspection posts; collection of fees.* .....

Comments: .....

5 Legal publication

Procedures for legal publication: .....

Title of the official publication: .....

Are the Veterinary Services subscribers? ..... Yes ..... ☐ ..... No ..... ☐

Is there a system of internal circulation? ..... Yes ..... ☐ ..... No ..... ☐

This question is to find out whether the official publication is circulated to the departments responsible for using it.

6 Are there rules for disseminating veterinary legislation other than by legal publication?

The publication of legal instruments is usually governed by the Constitution or the law. In addition, there may be regulations or administrative instructions to ensure a wider or more targeted dissemination (e.g. via official bulletins or the press). This question is aimed at identifying the formal arrangements that exist.

Informal arrangements can be mentioned. In this case, please enter "non-formalised" under the heading "Reference of the rules".

Within the Veterinary Services: ..... Yes ..... ☐ ..... No ..... ☐

Example: weekly internal memorandum circulated to all departments with details of all new legal instruments.

To other administrations: ..... Yes ..... ☐ ..... No ..... ☐

To organised groups of stakeholders: ..... Yes ..... ☐ ..... No ..... ☐

To the public: ..... Yes ..... ☐ ..... No ..... ☐

Example: Veterinary Services' website, information bulletin, etc.

UNOFFICIAL VERSION

If you answered "Yes":

Reference document setting out the rules: .....

Method of dissemination: .....

Distribution lists: .....

Comments: .....

7 Rules for disseminating information that is subordinate and relevant to regulatory texts

Within the Veterinary Services: ..... Yes ..... ☐ ..... No ..... ☐

To other administrations: ..... Yes ..... ☐ ..... No ..... ☐

To organised groups of stakeholders: ..... Yes ..... ☐ ..... No ..... ☐

To the public: ..... Yes ..... ☐ ..... No ..... ☐

If you answered "Yes" to any question above:

Reference document setting out the rules: .....

Method of dissemination: e.g. *bulletin (printed or electronic), website* .....

Distribution lists: e.g. *professional lists, voluntary subscription.* .....

Rules regarding confidentiality: e.g. *list of confidential documents* .....

Comments: .....

UNOFFICIAL VERSION

Annex XXXIV (contd) / Annex IV (contd)

Q4 – Creation of legal instruments – methodology – legal drafting (legistics)

1. What is the procedure for creating and approving the primary legislation from inception to final enactment in your country? Identify all steps and the administrative divisions involved and the amount of time from inception to passage

2. What is the procedure for creating and approving the secondary legislation (regulations) in your country? Identify all steps and the administrative divisions involved and the amount of time from inception to passage

3 Are there formal rules for legal drafting? Yes ☐ No ☐

If "Yes", please indicate the reference:.....

Comments:

4 For the creation or updating of veterinary legislation:

Are the legal instruments always an initiative of the Veterinary Services?... ..... Yes .....☐ .....No ☐

Are legal experts involved at the design stage?..... ..... Yes .....☐ .....No ☐

Do veterinarians/other technical staff systematically work with the legal experts?.... Yes .....☐ .....No ☐

Comments: *Where appropriate, indicate the circumstances in which organisations other than the Veterinary Services have the initiative and at what point legal experts become involved, etc. …* .....

5 Is consultation undertaken during legal drafting?

With the public:..... Yes .... ☐ .....No.....☐

Is there a formal procedure? .....

With professionals:..... Yes .... ☐ .....No.....☐

Is there a formal procedure? .....

With other administrations:..... Yes .... ☐ .....No.....☐

Is there a formal procedure?

Comments:

By "procedure" we mean formally predetermined or systematic actions. Ad hoc consultations without a written report are not classified as procedures.

6 Is there a formal evaluation of the applicability and impact of the legal instruments as part of their creation (e.g. regulatory impact assessment)?

The question seeks to ascertain whether such a procedure exists, regardless of its form.

For primary legislation: Never ☐ . Sometimes.... ☐ Always .....☐

For secondary legislation: Never ☐ . Sometimes.... ☐ Always .....☐

For infra-regulatory text: Never ☐ . Sometimes.... ☐ Always .....☐

Comments: .....

This assessment may include cost benefit analysis, feasibility, environmental impact, cultural impact and/or unintended consequences.

In addition to the legislation, information may be provided on the procedures for its implementation. The administration can disseminate its operating rules, for example by means of a bulletin or periodic digests. Such information is known as infra-regulatory texts.

UNOFFICIAL VERSION

7 What do these evaluations usually take into account?

If a template exists for these evaluations, please attach it.

Comments: .....

8 Are performance indicators developed in parallel with the legal instruments to monitor the success of the legal provisions when they are implemented? Yes ☐ No ☐

The question seeks to ascertain whether the objectives of the measure (one or more legal instruments) have been formally quantified and whether indicators to measure them have been developed and implemented. A 'Yes' is taken to mean that checking against the indicators is done and recorded.

Comments: .....

9 Is there usually a timetable for implementation? Yes ☐ No ☐

For many measures, stakeholders and/or the administration will need time to introduce the necessary changes, particularly where there is a need for investment and training to meet new standards. The question seeks to ascertain whether a timetable for implementation is provided and progress monitored.

Comments: .....

10 When primary legislation is drafted, is the relevant secondary legislation drafted at the same time? ..... Yes .... ☐ .....No..... ☐

In most cases, significant legislative measures and decrees will require detailed implementing legal instruments but the procedures for their adoption may vary considerably in duration. Good legislation should be designed in its entirety, i.e. the implementing legal instruments are drafted at the same time as the source texts.

Comments: .....

UNOFFICIAL VERSION

Q5 – Definition of the veterinary domain and the division of responsibilities

A. Scope

The objective being to maintain control of health 'from the farm to the fork', the veterinary domain covers all actions designed to protect the health and welfare of animals and the health and safety of humans (e.g. relating to zoonotic diseases, food safety, dangerous animals). While administrative models may vary, all functions identified in the OIE Guidelines on Veterinary legislation should be addressed.

B. Objectives

The questionnaire establishes, for each component of veterinary legislation, how responsibilities are divided between the various administrations. This can help to identify redundancies, overlaps or gaps, as well as the lines of command. Please complete only those lines that are relevant and for which you have information.

Additional lines can be added, as appropriate.

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C. Questionnaire

Is the 'veterinary domain' defined for official purposes? Yes ☐ No ☐

If you answered "Yes", please state the definition and give the reference for the text:

No comments required.

For each domain, indicate the distribution of responsibilities

Domain			Legislation		Control		Ref. comments (8)
N°	category (2)	sub-category (3)	4	Authority responsible for preparation (5)	Control of 1st level (6)	Control of 2nd level (7)	
1a	Veterinary profession	Private sector	☐				
1b		Public sector	☐				
1c		Initial training	☐				
2a	Para-veterinary professionals	Public sector Private sector	☐				

Columns (1) to (3) identify the main domains and sub-domains. Additional lines can be inserted as and where appropriate, to include any other aspects of the veterinary domain covered in your country. To make it easier to identify any gaps, please do not remove any lines.

Tick the box in column (4) if your country has legislation relating to the domain in question. **If you tick this box**, please indicate in column (5) which authority initiates and prepares the regulations. In some cases, there may be more than one authority: if there is more than one authority, enter the names in the same cell.

Column (6) "1st level of control" identifies the body that directly controls implementation. This is usually an inspection service but could also be the private sector operators themselves, within the framework of compulsory auto-inspection, or delegated bodies (e.g. independent inspection offices).

Answer "No" if there is no 1st level of control. Control may be performed concurrently by several different authorities. If this is the case, please list them in the same cell.

The 2nd level of control (column 7) may not exist in all cases. Control may be performed by a local authority, the central authority, a general inspection service, etc. Please enter "No" if it does not exist.

In column (8) indicate the reference legal instruments that assign authorities. If there is insufficient space this information can be given in an appendix (include a cross-reference in appropriate cell in column 8).

UNOFFICIAL VERSION

Q6 – Inspectors

	(1) Objectives	(2)	Legal basis			(6) Comments
			(3) Primary legislation	(4) Secondary legislation	(5) Infra-regulatory texts	
1	Inspectors have a defined field of intervention	☐				
2	Inspectors have a defined intervention territory	☐				
	….					
16	Stakeholders have the right of appeal against administrative decisions	☐				

For each line, please indicate in column 2 if the measure exists officially. If the measure is performed without any formal basis, do not tick the box but give details in the form of a comment.

If there is an official (legal) basis, please specify the legal instruments according to their categories in columns 3 to 5. A single item may be based on several legal instruments in series and there may be references in more than one column for any given measure.

Note:

Definitions in lines 1 and 2 may be related to the inspectors' rank or qualifications. Details are not required here. They can be indicated in a comment.

Lines 3 to 6 distinguish between inspectors' legal policing powers and their administrative and enforcement powers, as opposed to the list of procedures in the following lines.

Lines 7 to 16: the aim is to identify whether there are inspectors with these powers. A given inspector may only have some of the listed competencies. In a comment, please state "some" or "all", depending on whether the power is granted to all inspectors or only to certain categories.

UNOFFICIAL VERSION

Q7 – Financial framework

1 Central Veterinary Services

What proportion of the budget for Central Veterinary Service come from each of the following sources:

annual State budget..... %

.....

Fees paid to the government for services ..... %

.....

Other sources of income (e.g. international donors, industry)..... %

.....

Comments: .....

2 Territorial Veterinary Services

What proportion of the budget for Territorial Veterinary Service come from each of the following sources

annual State budget..... %..... %

fees paid to the government for services..... %..... %

territorial budgets ..... %..... %

Other sources of income..... %

..... %

Comments: .....

3 Are fees paid for any of the following services?

Action		% retained by the Vet. Services
Inspection of animals, meat or other products	☐	
Processing applications e.g. for approval, authorisation, licensing	☐	
Export certification	☐	
Import controls	☐	
Diagnostic testing	☐	
Sale of other services or products	☐	

UNOFFICIAL VERSION

4 Numerical data:

Criterion	Absolute value	%
National GDP		100
Livestock sector as a percentage of national GDP		
Agri-food sector as a percentage of national GDP		
State national budget *		100
VS budget as a percentage of the State budget *		

* including total payroll

UNOFFICIAL VERSION

OIE Support Programme for Veterinary Legislation

Preparatory Questionnaire Part II:

Technical Recommendations

Introduction

This questionnaire part II closely follows the specific points presented in the OIE Guidelines for Veterinary Legislation. The numbering presented in this questionnaire corresponds to the matching section in the Guidelines for your reference. With reference to each point, please indicate if that point has been addressed in your country legislation (Done), has not been addressed (Not done) or has been partially addressed (Partially done). Then, when appropriate, please provide explanatory comments that include reference to the specific legislative acts or regulations that fully or partially address the particular point.

An example is given here. It is taken from the completed questionnaire submitted by another country in advance of their legislative mission:

---

6. Health provisions relating to animal production

6.1 Identification and traceability

Veterinary legislation should address the following elements:

i) the objectives and scope of animal identification:

Done: ☐ Not done: ☐ Partially done: ☒

Comments:

Partially done. The Animal Diseases Act Section 18 (e) and its Statutory Instrument 38-4 Second Schedule require mandatory identification of animals and animal products being moved under a movement permit for animal health purposes. Here, the owner, area of origin for animal items, type of animals, quantities and area of final destination are required.

The Animal Breeding Act Sections 6, 12 and 48(2) requires registration, certification and recording and marking animals for breeding purposes only.

UNOFFICIAL VERSION

Preparatory Questionnaire Part II:

Technical Recommendations

3. Veterinary and Para-veterinary professions

3.1 Veterinary medicine

In order to ensure the quality of veterinary medicine, the veterinary legislation should:

i) provide an official definition of veterinary medicine:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……

ii) Define the prerogatives of the professionals involved in the practice of veterinary medicine:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

iii) Define the minimum initial and continuous educational requirements for the professionals:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

iv) Prescribe the conditions for recognition of diplomas for veterinarians and Para veterinarians:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

UNOFFICIAL VERSION

v) Define the conditions for the exercise / practice of veterinary and Para-veterinary professions:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

vi) Define the professional responsibilities of veterinarians and persons working under their control:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

vii) Prescribe the situations where persons other than qualified veterinarians can undertake activities that are normally to be carried out by veterinarians e.g. in exceptional circumstances such as epizootics:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

3.2. The control of the professions.

In order to control the veterinary and Para-veterinary professions, the veterinary legislation should:

i) Describe the general system of control in terms of the political, administrative and geographic configuration of the State:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

UNOFFICIAL VERSION

ii) Provide for the possibility of the delegation of powers to a professional organization such as a veterinary statutory body:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

iii) Where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organization:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

iv) Prescribe the disciplinary powers that apply to the relevant professions:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
……
……
……
……

4. Laboratories in the veterinary field

4.1 Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

i) Reference laboratories, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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ii) Laboratories designated by the State for carrying out the analysis of official samples:

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iii) Laboratories recognized by the State as fit to conduct compulsory analyses by the private sector:

Done: ☐ Not done: ☐ Partially done: ☐

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iv) The veterinary legislation should define the conditions for the classification, approval, operations and supervision of laboratories at each level:

Done: ☐ Not done: ☐ Partially done: ☐

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4.2 Laboratory reagents –

Veterinary legislation should address the elements listed below:

i) procedures for authorizing the reagents that are used to perform official analyses:

Done: ☐ Not done: ☐ Partially done: ☐

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ii) Surveillance of marketing of reagents, where these can affect the quality of analyses required by the veterinary legislation:

Done: ☐ Not done: ☐ Partially done: ☐

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iii) Quality assurance of reagents by manufacturers:

Done: ☐ Not done: ☐ Partially done: ☐

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5. Delegation of powers

5.1 General principles

The veterinary legislation should provide for the possibility of the competent authorities delegating specific tasks related to official activities. The specific tasks delegated, the body(ies) to which the tasks are delegated and the conditions of supervision by the competent authority should be defined.

Done: ☐ Not done: ☐ Partially done: ☐

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5.2 Animal health delegation

The veterinary legislation should provide for the possibility of the competent authority delegating specific tasks in the sector of animal health to individual professional veterinarians who are not civil servants.

For that purpose the veterinary legislation should:

i) define the field of activities and the specific tasks covered by the delegation:

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ii) provide for the control, supervision and financing of the delegation:

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iii) define the procedures for making delegations:

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iv) define the competencies to be held by persons receiving delegation:

Done: ☐ Not done: ☐ Partially done: ☐

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v) define the conditions of withdrawals of delegations:

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5.3 Delegation of functions relating to veterinary certification

Veterinary legislation should conform with Section 5 of the OIE *Terrestrial Code* concerning certification procedures, especially on the:

i) conditions of appointment or recognition of certifying officials:

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Comments:……
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ii) role and responsibilities of the certifying officials:

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iii) conditions of certification:

Done: ☐ Not done: ☐ Partially done: ☐

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iv) means of supervision and financing of certification:

Done: ☐ Not done: ☐ Partially done: ☐

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v) define the conditions of withdrawal of the delegation:

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5.4 Delegation of functions relating to the identification of animals and traceability

i) Veterinary legislation should provide for the possibility of delegating operations, under the supervision of the competent authority, to the operators that are best placed to carry out and manage the identification systems:

Done: ☐ Not done: ☐ Partially done: ☐

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ii) Veterinary legislation should define the conditions of withdrawal of the delegation:

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5.5 Relationships with stakeholders

To ensure transparency and facilitate implementation of the veterinary legislation, the competent authority should establish relationships with stakeholders, including by:

i) taking steps to ensure that stakeholders participate in the development of significant legislation and required follow up:

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ii) supporting, as appropriate, participation of stakeholders in international discussions:

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6. Health provisions relating to animal production

6.1 Identification and traceability

Veterinary legislation should address the following elements:

i) the objectives and scope of animal identification:

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ii) the possibility to make animal identification compulsory for certain species, regions or function:

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iii) the power of the competent authority to control movements of animals and changes of ownership:

Done: ☐ Not done: ☐ Partially done: ☐

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iv) the identification includes the marking of animals or groups of animals and the recording of corresponding data:

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v) the use of identification data for veterinary matters:

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vi) the equipment and methods to be used and the qualifications of operators for the marking or tracing of animals as appropriate to each situation:

Done: ☐ Not done: ☐ Partially done: ☐

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vii) the type of data to be recorded and the responsibilities of each party, notably those of animal keepers:

Done: ☐ Not done: ☐ Partially done: ☐

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viii) for the conduct of checks and corrections, as may be required to ensure the reliability of information in the database, notably in respect of animals that have died or have been slaughtered for any reason:

Done: ☐ Not done: ☐ Partially done: ☐

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ix) respect for constitutional liberties by restricting the use, security and confidentiality of data:

Done: ☐ Not done: ☐ Partially done: ☐

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6.2 Animal markets and other gatherings

Veterinary legislation should address the following elements:

i) registration of all permanent or temporary animal markets and other animal gatherings;

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ii) health measures to prevent disease transmission, including procedures for cleaning and disinfection, and animal welfare measures:

Done: ☐ Not done: ☐ Partially done: ☐

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iii) provision for compulsory veterinary checks at animal gatherings:

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6.3 Animal reproduction

Except where the animals or reproductive material are only used in a single holding, the veterinary legislation should address the elements listed below:

UNOFFICIAL VERSION

i) the health regulation of animal reproduction as appropriate:

Done: ☐ Not done: ☐ Partially done: ☐

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ii) health regulations may be implemented at the level of animals, genetic material, establishments or operators:

Done: ☐ Not done: ☐ Partially done: ☐

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6.4 Animal feed

Veterinary legislation should address the elements listed below:

i) standards for the production and composition of animal feed:

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ii) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations:

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iii) recall from the market of any product likely to present a hazard to human health or animal health.

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6.5 Animal by-products (i.e. products not used for human consumption)

Veterinary legislation should address the elements listed below:

i) definition of the animal by-products subject of the legislation:

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ii) rules for collection, processing methods and authorized uses of animal by-products:

Done: ☐ Not done: ☐ Partially done: ☐

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iii) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations:

Done: ☐ Not done: ☐ Partially done: ☐

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iv) definition of the rules to be applied by animal owners as appropriate:

Done: ☐ Not done: ☐ Partially done: ☐

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6.6 Disinfection

Veterinary legislation should address the following elements:

i) the regulation of products and methods that are used for disinfection relating to animal diseases:

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ii) the use of disinfection at all critical points, notably during the transportation of animals:

Done: ☐ Not done: ☐ Partially done: ☐

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7. Animal diseases

7.1 Surveillance

Veterinary legislation should address the following elements:

i) collection, transmission and utilisation of epidemiological data relevant to listed diseases:

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ii) an early warning system:

Done: ☐ Not done: ☐ Partially done: ☐

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7.2 Disease prevention:

Veterinary legislation should address the following elements:

i) specific rules for each listed disease:

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ii) support to stakeholders in proposing joint programs:

Done: ☐ Not done: ☐ Partially done: ☐

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iii) the direct control by the competent authority of some disease prevention programmes:

Done: ☐ Not done: ☐ Partially done: ☐

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iv) compulsory programmes for some disease prevention when necessary:

Done: ☐ Not done: ☐ Partially done: ☐

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7.3 Disease control

Veterinary legislation should address the following elements:

i) different lists of diseases, with provision (as appropriate) for:

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- emergency measures in accordance with established contingency plans:

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- measures for prevention, control or eradication:

Done: ☐ Not done: ☐ Partially done: ☐

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- surveillance measures:

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ii) the specification of mandatory control measures for certain diseases:

Done: ☐ Not done: ☐ Partially done: ☐

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iii) arrangements for the declaration of animal diseases including on the grounds of suspicion:

Done: ☐ Not done: ☐ Partially done: ☐

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iv) immediate technical measures including on the grounds of suspicion:

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v) measures for official disease surveillance:

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vi) conditions for confirmation of diseases:

Done: ☐ Not done: ☐ Partially done: ☐

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vii) precautionary measures.

Done: ☐ Not done: ☐ Partially done: ☐

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Veterinary legislation should provide for the following general measures:

i) definition of areas in which health measures are applied:

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ii) official publicizing of measures:

Done: ☐ Not done: ☐ Partially done: ☐

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iii) listing of all measures requiring a legal basis:

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iv) measures to be implemented by the public force;

Done: ☐ Not done: ☐ Partially done: ☐

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v) epidemiological investigations:

Done: ☐ Not done: ☐ Partially done: ☐

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vi) provisions for wild or protected animals:

Done: ☐ Not done: ☐ Partially done: ☐

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vii) conditions for restocking:

Done: ☐ Not done: ☐ Partially done: ☐

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viii) commercial restrictions:

Done: ☐ Not done: ☐ Partially done: ☐

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Contingency plan should be developed for certain diseases and, in addition to the general measures, should provide for:

i) administrative and logistic organization:

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ii) exceptional powers of the competent authority:

Done: ☐ Not done: ☐ Partially done: ☐

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iii) special and temporary measures to address all identified risks to human or animal health:

Done: ☐ Not done: ☐ Partially done: ☐

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Veterinary legislation should provide for the financing of animal disease control measures, notably:

i) operational expenses:

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ii) production losses:

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iii) owners compensation in the event of killing or slaughtering of animals, seizure or destruction of carcasses, meat, animal feed or other things:

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8. Animal welfare measures

8.1 General provisions

Veterinary legislation should address the elements listed below:

i) general principles to ensure the protection of animals against cruelty, abuse, abandonment and avoidable suffering, in line with the OIE *Terrestrial Code*:

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ii) legal definition of cruelty as an offense, subject to penal action:

Done: ☐ Not done: ☐ Partially done: ☐

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iii) direct intervention of the competent authority in the case of neglect by animal keepers:

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iv) accepted practices for livestock, pets, animals used in scientific experiments, sport and leisure, and for wild animals, notably in relation to:

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- transport and handling:

Done: ☐ Not done: ☐ Partially done: ☐

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- animal production and housing:

Done: ☐ Not done: ☐ Partially done: ☐

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- slaughtering and killing:

Done: ☐ Not done: ☐ Partially done: ☐

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- scientific experiments:

  Done: ☐ Not done: ☐ Partially done: ☐

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- use in games, shows, exhibitions and zoos:

  Done: ☐ Not done: ☐ Partially done: ☐

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v) certain activities relating to animals may be restricted to the holders of appropriate qualifications or approvals:

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8.2 Free-roaming and stray domestic animals

Veterinary legislation should address the elements listed below:

i) prohibition of abandonment of animals and of allowing animals to stray:

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ii) establishments where stray animals can be held and the conditions governing their operation:

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iii) the circumstances and the conditions of capture and of holding of stray animals:

Done: ☐ Not done: ☐ Partially done: ☐

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iv) the outcomes for these animals, including arrangements for veterinary interventions (including euthanasia in compliance with OIE standards), and for the transfer of ownership:

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9. Veterinary products (medicines, vaccines, chemicals, reagents)

9.1 Objectives

Veterinary legislation should address the following elements:

i) avoiding the presence of harmful residues in the food chain:

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ii) ensuring that the use of veterinary products does not give rise to human health risks:

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9.2 General measures

Veterinary legislation should address the elements listed below:

i) definition of veterinary products, including any specific exclusions:

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ii) regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary products:

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9.3 Raw materials and veterinary products

Veterinary legislation should address the elements listed below:

i) quality standards for raw materials used in the manufacture or composition of veterinary products and arrangements for checking quality:

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ii) establishment of the withdrawal periods and maximum residue limits for veterinary products as appropriate:

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iii) requirements for any substances that may interfere with the conduct of veterinary checks:

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9.4 Authorisation of veterinary products

Veterinary legislation should ensure that only authorised veterinary products may be placed on the market.

Special provisions should be made for:

i) veterinary products that do not present any risk of residues or interference with the conduct of disease prevention and control programmes:

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ii) medicated feed:

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iii) products prepared by veterinarians or pharmacists:

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iv) emergencies and temporary situations.

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Veterinary legislation should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.

In defining the procedures for seeking and granting authorisations, the legislation should:

i) describe the functioning of the competent authority concerned:

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ii) establish rules providing for the transparency of decisions:

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Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries:

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9.5 Quality of veterinary products

To give effect to the objectives identified above, veterinary legislation should address the elements listed below:

i) the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer, including analysis and dosage methods:

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ii) conditions for the conduct of trials:

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iii) qualifications of experts involved in trials:

Done: ☐ Not done: ☐ Partially done: ☐

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iv) surveillance for adverse effects arising from the use of veterinary products:

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9.6 Establishments producing, storing and selling veterinary products

Veterinary legislation should address the following elements:

i) registration or authorisation of all operators importing, storing, processing, selling or otherwise distributing veterinary products or raw materials for use in making veterinary products:

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ii) definition of the responsibilities of operators:

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iv) good manufacturing practices as appropriate:

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v) arrangements for informing the competent authority about traceability of products and adverse effects:

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9.7 Commerce, distribution, use and traceability of veterinary products

Veterinary legislation should address the following elements:

i) control over the circulation and distribution of veterinary products and arrangement for traceability and condition of use:

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ii) establishment of rules of prescription and provision of veterinary products to the end user:

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iii) restricting to authorised professionals all commerce in veterinary products that are subject to prescription:

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iv) the supervision by an authorised professional of organisations approved for holding and use of veterinary products:

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v) the regulation of advertising claims and other marketing and promotional activities:

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10. Safeguards for the food production chain and traceability

10.1 Objectives

Veterinary legislation should address the following elements:

i) the control of the manufacturing process at all relevant levels in the food production chain:

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ii) requirements to assure food safety for the purpose of human health:

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10.2 General

Veterinary legislation should address the following elements in order to ensure the food safety of animal products:

i) recording all significant health events that occur during primary production:

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ii) prohibition of the marketing of infected products or products likely to be contaminated or hazardous for the consumer or for animal health:

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iii) inspection for food safety and food composition:

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iv) inspection of premises:

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v) controls over the implementation of the legislation at all stages of the production, processing and distribution of food of animal origin:

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vi) establish that operators of food production premises have the primary responsibility for food safety:

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vii) obligations for producers to withdraw from the marketplace all products likely to be hazardous for human or animal health:

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10.3 Products of animal origin intended for human or animal consumption

Veterinary legislation should address the following elements:

i) arrangements for inspection;

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ii) the conduct of inspection on the basis of veterinary expertise:

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iii) relevant health standards:

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iv) application of health identification marks, which are visible to the intermediary or final user:

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The competent authority should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

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10.4 Premises and establishments pertaining to the food chain Veterinary legislation should address the following elements as appropriate:

i) recording the coordinates of operators working within the food chain:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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ii) the implementation by operators of procedures based on HACCP principles:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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iii) prior authorisation of operators whose activities are likely to constitute a significant risk to human or animal health:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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11. International movements and trade

11.1 Importation

Veterinary legislation should address the following elements:

i) the coordinates of importers and, as appropriate, their approval by the competent authority of the importing country:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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ii) the approval of establishments by the competent authority of:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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- the list of goods to be subject to veterinary checks:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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- the importation check points officially designated for each kind of goods:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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- the kinds and procedures of checks to be performed:

Done: ☐ Not done: ☐ Partially done: ☐

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Comments:……
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- the standards with which animals and commodities proposed for importation must comply:

  Done: ☐ Not done: ☐ Partially done: ☐

  Comments:……
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iii) prevention of entry of listed goods and consignments into the country unless such goods have been subjected to the required veterinary checks;

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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iv) objectivity and independence of inspectors:

Done: ☐ Not done: ☐ Partially done: ☐

Comments:……
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11.2 Exports

Veterinary legislation should specify the conditions governing the provision of veterinary certification and any prohibitions, in conformity with relevant provisions of the OIE and of the Codex Alimentarius Commission. It should also include provisions ensuring national involvement to relevant activities of the work of the OIE and the Codex Alimentarius and, if necessary, inter-ministerial coordination allowing the harmonization of the positions taken by the country in these international organizations.

Done: ☐ Not done: ☐ Partially done: ☐

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Comments:……
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Annex XXXV

CHAPTER 6.10.

RISK ANALYSIS ~~ASSESSMENT~~ FOR ANTIMICROBIAL RESISTANCE ARISING FROM THE USE OF ANTIMICROBIAL AGENTS IN ANIMALS

Article 6.10.1.

Recommendations for analysing the risks to animal and human ~~public~~ health from antimicrobial resistant microorganisms of animal origin

1. Introduction

Problems related to antimicrobial resistance are inherently linked to *antimicrobial agent* use in any environment, including human and non-human usages. However the emergence or dissemination of antimicrobial resistance can occur or be influenced by ~~through~~ factors other than the use of *antimicrobial agents*.

The use of *antimicrobial agents* for ~~therapy~~ therapeutic and non therapeutic purposes ~~, prophylaxis and growth promotion~~ in *animals* can reduce their efficacy in animal and human medicine, through the development of ~~antimicrobial~~ resistant strains of pathogenic microorganisms. This *risk* may be represented by the loss of therapeutic efficacy of one or several *antimicrobial agents* ~~drugs~~ ~~and includes the selection and dissemination of antimicrobial resistant micro-organisms~~ ~~emergence of multi-resistant micro-organisms~~.

2. Objective

For the purpose of this chapter, the principal aim of *risk analysis*~~, for the purpose of this chapter, for antimicrobial resistance in micro-organisms from *animals*~~ is to provide OIE Members~~s~~ Countries with a transparent, objective and scientifically defensible method of assessing and managing the human and animal health *risks* associated with the development of resistance arising from the use of *antimicrobial agents* in *animals*.

Guidance on the issue of foodborne antimicrobial resistance related to the non-human use of *antimicrobial agents* is covered by the Codex Guidelines for risk analysis of foodborne antimicrobial resistance (CAC/GL77-2011).

3. The risk analysis process

The principles of *risk analysis* are described in Chapter 2.1. ~~Section~~ of this ~~*Terrestrial Code*~~. The components of *risk analysis* described in this chapter are *hazard identification*, *risk assessment*, *risk management* and *risk communication*.

The chapter includes factors to be considered at various steps of the *risk analysis* process. These factors are not intended to be exhaustive and not all elements may be applicable in all situations.

~~A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a quantitative risk assessment is feasible and/or necessary.~~

4. Hazard identification

Hazard identification is defined ~~under the OIE *Terrestrial Code*~~ in Chapter 2.1.

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Annex XXXV (contd)

For the purpose of this chapter, the *hazard* is the resistant microorganism or resistance determinant that emerges as a result of the use of a specific *antimicrobial agent* in *animals*. This definition reflects the ~~development of resistance in a species of pathogenic micro-organisms, as well as the development of a resistance determinant that may be passed from one species of micro-organisms to another~~ potential for resistant microorganisms to cause adverse health effects, as well as the potential for horizontal transfer of genetic determinants between microorganisms. The conditions under which the *hazard* might produce adverse consequences include any scenarios through which humans or *animals* could become exposed to an antimicrobial resistant pathogen ~~which contains that resistance determinant~~, fall ill and then be treated with an *antimicrobial agent* that is no longer effective ~~because of the resistance~~.

5. Risk assessment

The assessment of the *risk* to human and animal health from antimicrobial-resistant microorganisms resulting from the use of *antimicrobial agents* in *animals* should examine:

a) the likelihood of emergence of resistant microorganisms arising from the use of *antimicrobial agent*(s), or more particularly, dissemination ~~production~~ of the resistance determinants if transmission is possible between microorganisms;

b) consideration of all pathways and their importance, by which humans and *animals* could be exposed to these resistant microorganisms or resistance determinants, together with the ~~possible degree~~ likelihood of exposure;

c) the consequences of exposure in terms of *risks* to human and~~/or~~ animal health.

The general principles of *risk assessment* as defined in Chapter 2.1. ~~of the *Terrestrial Code*~~ apply~~ies~~ equally to both qualitative and quantitative *risk assessment*. At a minimum, a qualitative *risk assessment* should always be undertaken.

Article 6.10.2.

Analysis of risks to human health

1. Definition of the risk

The *infection* of humans with microorganisms that have acquired resistance to a specific *antimicrobial agent* due to ~~the~~ its used in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the human *infection*.

2. Hazard identification

- Microorganisms that have acquired resistance, (including multiple resistance) arising from the use of an *antimicrobial agent*(s) in *animals*.

- Microorganisms having obtained a resistance determinant(s) from other microorganisms which have acquired resistance arising from the use of an *antimicrobial agent(s)* in *animals*.

The identification of the *hazard* ~~must~~ should include consideration of the class or subclass of the *antimicrobial agent(s)*. This definition should be read in conjunction with point 4~~)~~ of Article 6.10.1.

3. Release assessment

A release assessment describes the biological pathways necessary to lead to the release of resistant microorganisms or resistance determinants into a particular environment due to ~~for~~ the use of a specific *antimicrobial agent* in *animals* ~~to lead to the release of resistant micro-organisms or resistance determinants into a particular environment,~~. It also estimates ~~and estimating~~ either qualitatively or quantitatively the probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential *hazards* under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

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The following factors should be considered in the release assessment:

- animal species and, where appropriate, production type (e.g. veal calves or dairy cattle, broilers or laying hens) ~~of animal~~ treated with the *antimicrobial agent(s)* in question;
- number of *animals* treated, sex, age and their geographical distribution ~~of those *animals*~~;
- prevalence of *infection* or *disease* for which the *antimicrobial agent* is indicated in the target animal population;
- data on trends in *antimicrobial agent* use and changes in farm production systems;
- data on ~~potential~~ extra-label or off-label use;
- ~~variation in~~ methods and routes of administration of the *antimicrobial agent(s)*;
- dosage regimen (dose, dosing interval and duration of the treatment) ~~including duration of use~~;
- ~~the~~ pharmacokinetics or pharmacodynamics~~/pharmacokinetics~~ of the *antimicrobial agent(s)*;
- ~~micro-organisms developing resistance as a result of the antimicrobial(s) use~~ prevalence of pathogens that are likely to acquire resistance in animal host;
- commensal bacteria which are able to transfer resistance to human pathogens;
- mechanisms and pathways of direct or indirect transfer of resistance;
- potential linkage of virulence attributes and resistance;
- cross-resistance ~~and/~~or co-resistance with other *antimicrobial agents*;
- data on occurrence of resistant microorganisms through surveillance of *animals*, products of animal origin and animal waste products ~~for the existence of resistant micro-organisms~~.

4. Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant microorganisms or resistance determinants released from a given antimicrobial use in *animals*, and estimating the probability of the exposures occurring. The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure and the number, species and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:

- human demographics, including population subgroups, and food consumption patterns, including traditions and cultural practices in respect to the preparation and storage of food;
- prevalence of resistant microorganisms in food at the point of consumption or exposure;
- microbial load in contaminated food at the point of consumption or exposure ~~for quantitative risk assessment~~;

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Annex XXXV (contd)

- environmental contamination with resistant microorganisms;
- occurrence of resistant microorganisms in animal feed ~~prevalence of animal feed contaminated with resistant micro-organisms~~;
- transfer ~~cycling~~ of resistant microorganisms between humans, *animals* and the environment;
- ~~steps~~ measures taken for ~~of~~ microbial decontamination of food;
- ~~microbial load in contaminated food at the point of consumption;~~
- survival capacity and spread ~~redistribution~~ of resistant microorganisms during the food production process (including slaughtering, processing, storage, transportation and retailing);
- disposal practices for waste products and the opportunity for human exposure to resistant microorganisms or resistance determinants in those waste products;
- ~~point of consumption of food (professional catering, home cooking);~~
- ~~variation in consumption and food-handling methods of exposed populations and subgroups of the population;~~
- capacity of resistant microorganisms to become established in humans;
- human-to-human transmission of the microorganisms under consideration;
- capacity of resistant microorganisms to transfer resistance to human commensal microorganisms and zoonotic agents;
- amount and type of *antimicrobial agents* used in response to human illness;
- pharmacokinetics (such as metabolism, bioavailability and, access to intestinal flora).

5. Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant microorganisms or resistance determinants and the consequences of those exposures. A causal process ~~must~~ should exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

The following factors should be considered in the consequence assessment:

- microbial dose – host response relationships;
- variation in susceptibility of exposed populations or subgroups of the population;
- variation and frequency of human health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- ~~changes in human medicinal practices resulting from reduced confidence in antimicrobials;~~
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary *risks*;

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- ~~associated costs;~~

- interference with first-line or /choice antimicrobial therapy in humans;

- importance of the *antimicrobial agent* in human medicine ~~perceived future usefulness of the antimicrobial (time reference)~~;

- prevalence of resistance in human bacterial pathogens under consideration.

6. Risk estimation

A *risk* estimation integrates the results from the release assessment, exposure assessment and consequence assessment to produce overall estimates of *risks* associated with the *hazards*. Thus, *risk* estimation takes into account the whole of the *risk* pathway from *hazard identification* to the unwanted consequences.

The following factors should be considered in the *risk* estimation:

- number of people falling ill and the proportion of that number infected ~~affected~~ with antimicrobial resistant ~~strains of~~ microorganisms;

- adverse effects on vulnerable human sub-population (children, immunocompromised persons, elderly, etc.);

- increased severity or duration of infectious *disease*;

- number of person-/ ~~or~~ days of illness per year;

- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population);

- ~~importance~~ severity of the ~~pathology~~ *disease* ~~infection~~ caused by the target microorganisms;

- availability ~~existence or~~ ~~absence~~ of alternative antimicrobial therapy;

- potential impact of switching to an alternative *antimicrobial agent* (e.g. alternatives with potential increased toxicity);

- occurrence ~~incidence~~ of antimicrobial resistance in target pathogens observed in humans;

- consequences of the overall ~~to allow weighted summation of different~~ *risk* impacts (e.g. illness and hospitalisation).

7. Risk management components ~~options and risk communication~~

The OIE defines risk management as consisting of the steps described below. ~~Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.~~

a) Risk evaluation – the process of comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection.

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Annex XXXV (contd)

b) Option evaluation

A range of risk management options is available to minimise the emergence and spread of antimicrobial resistance and these include both regulatory and non-regulatory ~~risk management~~ options, such as the development of codes of practice ~~concerning~~ for the use of *antimicrobial agent*s in animal husbandry. *Risk management* decisions need to consider fully the implications of these different options for human health and animal health and welfare and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial diseases of *animals* will have the dual benefit of reducing the risks linked to antimicrobial resistance, in cases where the ~~bacterial disease~~ pathogen under consideration has also developed antimicrobial resistance.

c) Implementation

Risk managers should develop an implementation plan that describes how the decision will be implemented, by whom and when. ~~National or regional authorities~~ *Competent Authorities* should ensure an appropriate regulatory framework and infrastructure.

d) Monitoring and review

Risk management options ~~have to~~ should be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

8. Risk communication

Communication with all interested parties should be promoted at the earliest opportunity and integrated into all phases of a *risk analysis*. This will provide all interested parties, including risk managers, with the better understanding of risk management approaches. Risk communication should be also well documented.

Article 6.10.3.

Analysis of risks to animal health

1. Definition of the risk

The *infection* of *animals* with microorganisms that have acquired resistance to ~~from the use of~~ a specific *antimicrobial agent*~~(s)~~ due to ~~the~~ its use in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal *infection*.

2. Hazard identification

- m~~M~~icroorganisms that have acquired resistance, (including multiple resistance) arising from the use of an *antimicrobial agent(s)* in *animals*;

- m~~M~~icroorganisms having obtained a resistance determinant(s) from another microorganism~~s~~ which has~~ve~~ acquired resistance arising from the use of an *antimicrobial agent(s)* in *animals*.

The *identification of the hazard* ~~must~~ should include considerations of the class or subclass of the *antimicrobial agent(s)*. This definition should be read in conjunction with point 4~~)~~ of Article 6.10.1.

3. Release assessment

The following factors should be considered in the release assessment:

- animal species and, where appropriate, production type (e.g. veal calves or dairy cattle, broilers or laying hens) treated with the *antimicrobial agent(s)* in question;

- number of *animals* treated, sex, age and their geographical distribution;

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- prevalence of *infection* or *disease* for which the *antimicrobial agent* is indicated in the target animal population;
- data on trends in *antimicrobial agent* use and changes in farm production systems;
- potential extra-label or off-label use;
- dosage regimen including ~~amounts used and~~ duration of ~~treatment~~ use;
- ~~variation in~~ methods and routes of administration of the *antimicrobial agent(s)*;
- the pharmacokinetics or pharmacodynamics~~/ pharmacokinetics~~ of the *antimicrobial agent(s)*;
- site and type of *infection;*
- development of resistant microorganisms;
- mechanisms and pathways of resistance transfer;
- cross-resistance ~~and/~~or co-resistance with other *antimicrobial agents*;
- data on occurrence of resistant microorganisms through surveillance of *animals*, products of animal origin and animal waste products ~~for the existence of resistant micro-organisms~~.

4. Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant microorganisms in clinically ill and clinically unaffected *animals*;
- occurrence ~~prevalence~~ of resistant microorganisms in feed and in~~/~~ the animal environment;
- animal-to-animal transmission of the resistant microorganisms (animal husbandry practices ~~methods~~ , movement of *animals*);
- number~~/~~ or percentage of *animals* treated;
- ~~dissemination of resistant micro-organisms from *animals* (animal husbandry methods, movement of *animals*);~~
- quantity and trends of *antimicrobial agent(s)* used in *animals*;
- ~~treatment regimens (dose, route of administration, duration);~~
- survival capacity ~~of resistant micro-organisms~~ and spread of resistant microorganisms;
- exposure of *wildlife* to resistant microorganisms;
- disposal practices for waste products and the opportunity for animal exposure to resistant microorganisms or resistance determinants in those products;
- capacity of resistant microorganisms to become established in *animals* ~~intestinal flora~~;
- exposure to resistance determinants from other sources such as water, effluent, waste pollution, etc.;

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- ~~dose, route of administration and duration of treatment;~~
- pharmacokinetics, such as ~~(~~metabolism, bioavailability, access to intestinal flora~~)~~;
- transfer ~~cycling~~ of resistant microorganisms between humans, *animals* and the environment.

5. Consequence assessment

The following factors should be considered in the consequence assessment:

- microbial dose ~~-~~ host response relationships;
- variation in disease susceptibility of exposed populations and subgroups of the populations;
- variation and frequency of animal health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- ~~changes in practices resulting from reduced confidence in antimicrobials;~~
- ~~associated cost;~~
- ~~perceived future~~ importance ~~usefulness~~ of the ~~drug~~ *antimicrobial agent* in animal health (see OIE list of *antimicrobial agents* of veterinary importance) ~~(time reference)~~.

6. Risk estimation

The following factors should be considered in the *risk* estimation:

- additional burden of disease due to antimicrobial resistant microorganisms;
- number of therapeutic failures due to antimicrobial resistant microorganisms;
- increased severity and duration of infectious disease;
- impact on *animal welfare;*
- ~~economic cost;~~
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population);
- availability ~~existence or absence~~ of alternative antimicrobial therapy;
- potential impact of switching to an alternative *antimicrobial agent*, e.g. alternatives with potential increased toxicity;
- estimation of the economic impact and cost on animal health and production.
- ~~incidence of resistance observed in *animals*.~~

7. Risk management ~~options~~components ~~and risk communication~~

The relevant provisions contained in Article 6.9.7. do apply.

~~Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.~~

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~~The relevant recommendations (Articles 2.1.5., 2.1.6. and 2.1.7.) in the *Terrestrial Code* apply.~~

~~A range of *risk management* options is available to minimize the emergence and spread of antimicrobial resistance and these include both regulatory and non regulatory *risk management* options, such as the development of codes of practice concerning the use of antimicrobials in animal husbandry. *Risk management* decisions need to consider fully the implications of these different options for human health and animal health and *welfare* and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial *diseases* of *animals* will have the dual benefit of reducing the *risks* linked to antimicrobial resistance, in cases where the bacterial *disease* under consideration has also developed antimicrobial resistance. Appropriate communication with all stakeholders is essential throughout the *risk assessment* process.~~

8. Risk communication

The relevant provisions ~~contained~~ in Article 6.9.8. ~~do~~ apply.

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Annex XXXVI

CHAPTER 7.5.

SLAUGHTER OF ANIMALS

Article 7.5.1.

General principles

1. Object

These recommendations address the need to ensure the *welfare* of food *animals* during pre-slaughter and *slaughter* processes, until they are dead.

These recommendations apply to the *slaughter* in *slaughterhouses* of the following domestic *animals*: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and *poultry*. Other *animals*, wherever they have been reared, and all *animals* slaughtered outside *slaughterhouses* should be managed to ensure that their *transport*, *lairage*, *restraint* and *slaughter* is carried out without causing undue stress to the *animals*; the principles underpinning these recommendations apply also to these *animals*.

2. Personnel

Persons engaged in the *unloading*, moving, *lairage*, care, *restraint*, *stunning*, *slaughter* and bleeding of *animals* play an important role in the *welfare* of those *animals*. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the recommendations outlined in the present chapter and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of *animal welfare*.

3. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

The desire of some *animals* to control their personal space should be taken into account in designing facilities.

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans i.e. tame have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

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Animal handlers should use the point of balance at the *animal*'s shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Domestic *animals* have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although most domestic *animals* have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

4. Distractions and their removal

Distractions that may cause approaching *animals* to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

a) reflections on shiny metal or wet floors – move a lamp or change lighting;

b) dark entrances to chutes, races, stun boxes or conveyor restrainers – illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals* or create areas of sharp contrast;

c) *animals* seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;

d) dead ends – avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences – remove them;

f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;

g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of *animals* – redirect or reposition equipment.

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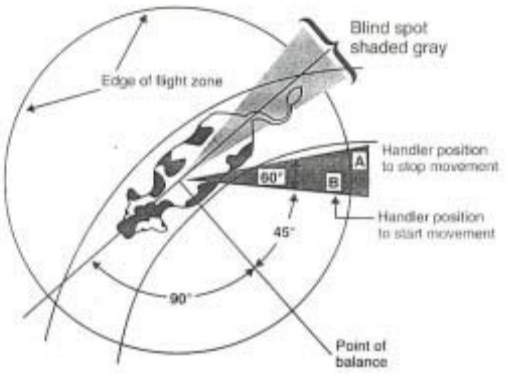
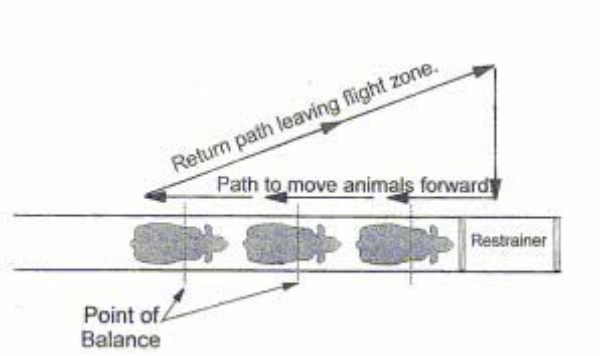
Annex XXXVI (contd)

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



Article 7.5.2.

Moving and handling animals

1. General considerations

Each *slaughterhouse* should have a dedicated plan for *animal welfare*. The purpose of such plan should be to maintain good level of *animal welfare* at all stages of the handling of *animals* until they are killed. The plan should contain standard operating procedures for each step of animal handling as to ensure that *animal welfare* is properly implemented based on relevant indicators. It also should include specific corrective actions in case of specific risks, like power failures or other circumstances that could negatively affect the *welfare* of *animals*.

Animals should be transported to *slaughter* in a way that minimises adverse animal health and *welfare* outcomes, and the transport should be conducted in accordance with the OIE recommendations for the transportation of *animals* (Chapters 7.2. and 7.3.).

The following principles should apply to *unloading animals*, moving them into *lairage* pens, out of the *lairage* pens and up to the *slaughter* point:

Annex XXXVI (contd)

a) The conditions of the *animals* should be assessed upon their arrival for any *animal welfare* and health problems.

b) Injured or sick *animals*, requiring immediate *slaughter*, should be killed humanely and without delay, in accordance with the recommendations of the OIE.

c) *Animals* should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of *animals* slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99 percent of *animals* without their falling.

d) *Animals* for *slaughter* should not be forced to walk over the top of other *animals*.

e) *Animals* should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move *animals*, such as crushing or breaking tails of *animals*, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to *animals* and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of *animals*, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small *animals* is permissible.

f) When using goads and other aids, the following principles should apply:

   i) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.

   ii) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

   iii) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.

   iv) Painful procedures (including whipping, kicking, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.

   v) Excessive shouting at *animals* or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.

   vi) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting such *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.

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vii) Conscious *animals* should not be thrown, dragged or dropped.

g) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling at a point in the *slaughterhouse*. Any risk of compromising *animal welfare*, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of *welfare* of the *animals*.

2. Specific considerations for poultry

Stocking density in transport crates should be optimum to suit climatic conditions and to maintain species-specific thermal comfort within *containers*.

Care is especially necessary during *loading* and *unloading* to avoid body parts being caught on crates, leading to dislocated or broken bones in conscious birds. Such injuries will adversely affect *animal welfare*, carcass and *meat* quality.

Modular systems that involve tipping of live birds are not conducive to maintaining good *animal welfare*. These systems, when used, should be incorporated with a mechanism to facilitate birds sliding out of the transport system, rather than being dropped or dumped on top of each other from heights of more than a metre.

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, constructed or maintained transport systems. Under this situation, operators *unloading* birds should ensure gentle release of trapped birds.

Drawers in modular systems and crates should be stacked and de-stacked carefully so as to avoid injury to birds.

Birds should have sufficient space so that all can lie down at the same time without being on top of each other.

Birds with broken bones and/or dislocated joints should be humanely killed before being hung on shackles for processing.

The number of *poultry* arriving at the processing plant with broken bones and/or dislocated joints should be recorded in a manner that allows for verification. For *poultry*, the percentage of chickens with broken or dislocated wings should not exceed 2 percent, with less than 1 percent being the goal (under study).

3. Provisions relevant to animals delivered in containers

a) *Containers* in which *animals* are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded and unloaded mechanically, and stacked to ensure ventilation. In any case they should be moved and stored in an upright position as indicated by specific marks.

b) *Animals* delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, *animals* should be unloaded from the *containers* individually.

c) *Animals* which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of *poultry* for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. *Animals* which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

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4. Provisions relevant to restraining and containing animals

a) Provisions relevant to *restraining animals* for *stunning* or *slaughter* without *stunning*, to help maintain *animal welfare*, include:

i) provision of a non-slippery floor;

ii) avoidance of excessive pressure applied by *restraining* equipment that causes struggling or vocalisation in *animals*;

iii) equipment engineered to reduce noise of air hissing and clanging metal;

iv) absence of sharp edges in *restraining* equipment that would harm *animals*;

v) avoidance of jerking or sudden movement of *restraining* device.

b) Methods of *restraint* causing avoidable suffering should not be used in conscious *animals* because they cause severe pain and stress:

i) suspending or hoisting *animals* (other than *poultry*) by the feet or legs;

ii) indiscriminate and inappropriate use of *stunning* equipment;

iii) mechanical clamping of the legs or feet of the *animals* (other than shackles used in *poultry* and ostriches) as the sole method of *restraint*;

iv) breaking legs, cutting leg tendons or blinding *animals* in order to immobilise them;

v) severing the spinal cord, for example using a puntilla or dagger, to immobilise *animals* using electric currents to immobilise *animals*, except for proper *stunning*.

Article 7.5.3.

Lairage design and construction

1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of *animals* in relation to the throughput rate of the *slaughterhouse* without compromising the *welfare* of the *animals*.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the *animals*, the *lairage* should be designed and constructed so as to allow the *animals* to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following recommendations may help to achieve this.

2. Design of lairage

a) The *lairage* should be designed to allow a one-way flow of *animals* from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.

b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of *animals* at any time, and to permit the removal of sick or injured *animals* when considered to be appropriate, for which separate appropriate accommodation should be provided.

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c) Each *animal* should have room to stand up and lie down and, when confined in a pen, to turn around, except where the *animal* is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious *animals* should be slaughtered as soon as possible after arrival at the *slaughterhouse* to avoid *welfare* problems. The *lairage* should have sufficient accommodation for the number of *animals* intended to be held. Drinking water should always be available to the *animals*, and the method of delivery should be appropriate to the type of *animal* held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in *animals*, and should not hinder the movement of *animals*.

d) Holding pens should be designed to allow as many *animals* as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all *animals* to feed. The feed trough should not hinder the movement of *animals*.

e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the *animals* and should also allow the *animals* to stand, lie down and access any food or water that may need to be provided.

f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent *animals* to see each other. For pigs and sheep, passageways should be wide enough to enable two or more *animals* to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the *animals*.

g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of *animals* to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of *animals* without injury.

h) In *slaughterhouses* with high throughput, there should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of *animals* for *stunning* or *slaughter* and to avoid having *animal handlers* trying to rush *animals* from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that *animals* cannot be trapped or trampled.

i) Ramps or lifts should be used for the *loading* and *unloading* of *animals* where there is a difference in height or a gap between the floor of the *vehicle* and the *unloading* area. Unloading ramps should be designed and constructed so as to permit *animals* to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent *animals* escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of *animals* without causing distress or injury.

3. Construction of lairage

a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the *animals*.

b) Floors should be well drained and not slippery; they should not cause injury to the feet of the *animals*. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where *animals* would have to cross them. Discontinuities or changes in floor, wall or gate colours, patterns or texture which could cause baulking in the movement of *animals* should be avoided.

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c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the *animals* or affect their movement. The fact that *animals* will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.

d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of *animals* the *lairage* will be expected to hold.

e) Care should be taken to protect the *animals* from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noises to the areas where *animals* are held and slaughtered.

f) Where *animals* are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 7.5.4.

Care of animals in lairages

Animals in *lairages* should be cared for in accordance with the following recommendations:

1) As far as possible, established groups of *animals* should be kept together and each *animal* should have enough space to stand up, lie down and turn around. *Animals* hostile to each other should be separated.

2) Where tethers, ties or individual stalls are used, they should allow *animals* to stand up and lie down without causing injury or distress.

3) Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the *animals*, and sufficient bedding should be used so that *animals* do not become soiled with manure.

4) *Animals* should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.

5) Suitable drinking water should be available to the *animals* on their arrival and at all times to *animals* in *lairages* unless they are to be slaughtered without delay.

6) Waiting time should be minimised and should not exceed 12 hours. If *animals* are not to be slaughtered within this period, suitable feed should be available to the *animals* on arrival and at intervals appropriate to the species. Unweaned *animals* should be slaughtered as soon as possible.

7) In order to prevent heat stress, *animals* subjected to high temperatures, particularly pigs and *poultry*, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of *animals* to thermoregulate (especially *poultry*) should be considered in any decision to use water sprays. The risk of *animals* being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.

8) The *lairage* area should be well lit in order to enable the *animals* to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all *animals*. Subdued lighting, and for example blue light, may be useful in *poultry lairages* in helping to calm birds.

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9) The condition and state of health of the *animals* in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian*'s responsibility, by another competent person, such as an *animal handler*. *Animals* which are sick, weak, injured or showing visible signs of distress should be separated, and veterinary advice should be sought immediately regarding treatment or the *animals* should be humanely killed immediately if necessary.

10) Lactating dairy *animals* should be slaughtered as soon as possible. Dairy *animals* with obvious udder distension should be milked to minimise udder discomfort.

11) *Animals* which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for their *welfare* and the *welfare* of the newborn. Under normal circumstances, *animals* which are expected to give birth during a *journey* should not be transported.

12) *Animals* with horns, antlers or tusks capable of injuring other *animals*, if aggressive, should be penned separately.

13) *Poultry* awaiting *slaughter* should be protected from adverse weather conditions and provided with adequate ventilation.

14) *Poultry* in transport *containers* should be examined at the time of arrival. *Containers* should be stacked with sufficient space between the stacks to facilitate inspection of birds and air movement.

15) Forced ventilation or other cooling systems may be necessary under certain conditions to avoid build up of temperature and humidity. Temperature and humidity should be monitored at appropriate intervals.

Recommendations for specific species are described in detail in Articles 7.5.5. ~~to~~ and 7.5.~~9~~6.

Article 7.5.5.

Management of foetuses during slaughter of pregnant animals

Under normal circumstances, pregnant *animals* that would be in the final 10 percent of their gestation period at the planned time of *unloading* at the *slaughterhouse* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately, and the specific procedures described below are applied. In all cases, the *welfare* of foetuses and dams during *slaughter* should be safeguarded.

Foetuses should not be removed from the uterus sooner than 5 minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-*slaughter* processing of pregnant *animals*, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15–20 minutes after the maternal neck or chest cut.

If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size or a blow to the head with a suitable blunt instrument.

The above recommendations do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at the evisceration of the dam, should not be attempted during normal commercial *slaughter* as it may lead to serious *welfare* complications in the newborn *animal*. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

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Article 7.5.6.

Summary analysis of handling and restraining methods and the associated animal welfare issues

[DELETE TABLE]

Article 7.5.~~7~~6.

Stunning methods

1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

a) the *animal* is adequately restrained;

b) *animals* in *restraint* are stunned as soon as possible;

c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the *animal*;

d) the equipment is applied correctly;

e) stunned *animals* are bled out (slaughtered) as soon as possible;

f) *animals* are not stunned when *slaughter* is likely to be delayed; and

g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails. Provision of a manual inspection area and simple intervention like captive bolt or cervical dislocation for *poultry* would help prevent potential *welfare* problems.

In addition, such persons should be able to recognise when an *animal* is not correctly stunned and should take appropriate action.

2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface.

For a more detailed explanation on the different methods for mechanical *stunning*, see Chapter 7.6. and Articles 7.6.~~6~~5., 7.6.~~7~~6. and 7.6.~~8~~7. The following diagrams illustrate the proper application of the device for certain species.

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Figure 1. The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Cattle

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

Pigs

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum position for hornless sheep and goats is on the midline.

Sheep

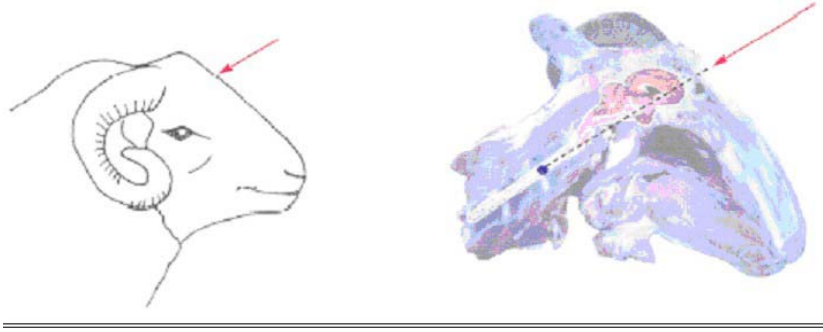

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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Figure 4. The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

Goats

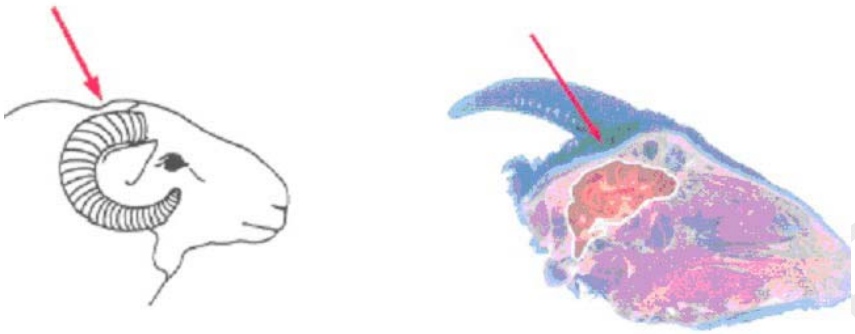

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 5. The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Horses

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Signs of correct *stunning* using a mechanical instrument are as follows:

1) the *animal* collapses immediately and does not attempt to stand up;

2) the body and muscles of the *animal* become tonic (rigid) immediately after the shot;

3) normal rhythmic breathing stops; and

4) the eyelid is open with the eyeball facing straight ahead and is not rotated.

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Figure 6. Poultry

Captive bolts powered by cartridges, compressed air or spring can be used for poultry. The optimum position for poultry species is at right angles to the frontal surface.

Firing of a captive bolt according to the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate death.

Poultry

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Poultry

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

~~Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.~~

~~Firing of a captive bolt according to the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.~~

3. Electrical stunning

a) General considerations

An electrical device should be applied to the *animal* in accordance with the following recommendations.

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Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the *animal* has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the *animal* is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on *animals* as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the *animal* before the actual *stunning* or *killing*.

Electrical *stunning* apparatus should be tested prior to application on *animals* using appropriate resistors or dummy loads to ensure the power output is adequate to stun *animals*.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective *stunning*.

The *stunning* apparatus should be appropriate for the species. Apparatus for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions. Minimum current levels for head-only *stunning* are shown in the following table.

Species	**Minimum current levels for head-only stunning**
Cattle	1.5 amps
Calves (bovines of less than 6 month of age)	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

b) Electrical stunning of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

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In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks. The shackle size should be appropriate to fit the size of the shanks (metatarsal bones) of birds.

Birds should be hung on shackles by both legs.

Birds with dislocated or broken legs or wings should be humanely killed rather than shackled.

The duration between hanging on shackles and *stunning* should be kept to the minimum. In any event, the time between shackling and *stunning* should not exceed one minute.

Waterbaths for *poultry* should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve the electrical conductivity of the water, it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may be required.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of *stunning* and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of birds that have not been effectively stunned reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately. The height of the waterbath stunner should be adjusted according to the size of birds to ensure even the small birds are immersed in the water bath up to the base of the wings.

Waterbath *stunning* equipment should be fitted with a device which displays and records the details of the electrical key parameter.

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Minimum current for *stunning poultry* when using 50Hz is as follows:

Species	Current (milliamperes per bird)
Broilers	100
Layers (spent hens)	100
Turkeys	150
Ducks and geese	130

Minimum current for *stunning poultry* when using high frequencies is as follows:

	Minimum current (milliamperes per bird)	
Frequency (Hz)	**Chickens**	**Turkeys**
From 50 to 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

4. Gas stunning (under study)

a) Stunning of pigs by exposure to carbon dioxide (CO_2)

The concentration of CO_2 for *stunning* should be preferably 90 percent by volume but in any case no less than 80 percent by volume. After entering the *stunning* chamber, the *animals* should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO_2 for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the *animal* prior to loss of consciousness.

The chamber in which *animals* are exposed to CO_2 and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the *animals*. The animal density within the chamber should be such to avoid stacking *animals* on top of each other.

The conveyor and the chamber shall be adequately lit to allow the *animals* to see their surroundings and, if possible, each other.

It should be possible to inspect the CO_2 chamber whilst it is in use, and to have access to the *animals* in emergency cases.

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The chamber shall be equipped to continuously measure and display register at the point of *stunning* the CO_2 concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO_2 falls below the required level.

Emergency *stunning* equipment should be available at the point of exit from the *stunning* chamber and used on any pigs that do not appear to be completely stunned.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to *animals*. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

i) a maximum of 2 percent by volume of oxygen in argon, nitrogen or other inert gases, or

ii) to a maximum of 30 percent by volume of carbon dioxide and a maximum of 2 percent by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious *poultry* under water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to *poultry*.

Live *poultry* contained within transport modules or crates may be exposed to gradually increasing concentrations of CO_2 until the birds are properly stunned. No bird should recover consciousness during bleeding.

Gas *stunning* of *poultry* in their transport *containers* will eliminate the need for live birds' handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of *poultry* on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Live *poultry* should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all *animals* are properly stunned without unnecessary suffering. Some monitoring points for gas *stunning* could be the following:

– ensure smooth entry and passage of crates or birds through the system;

– avoid crowding of birds in crates or conveyors;

– monitor and maintain gas concentrations continuously during operation;

– provide visible and audible alarm systems if gas concentrations are inappropriate to the species;

– calibrate gas monitors and maintain verifiable records;

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Annex XXXVI (contd)

– ensure that duration of exposure is adequate to prevent recovery of consciousness;

– make provision to monitor and deal with recovery of consciousness;

– ensure that blood vessels are cut to induce *death* in unconscious birds;

– ensure that all birds are dead before entering scalding tank;

– provide emergency procedures in the event of system failure.

i) Gas mixtures used for stunning *poultry* include:

– a minimum of 2 minutes exposure to 40 percent carbon dioxide, 30 percent oxygen and 30 percent nitrogen, followed by a minimum of one minute exposure to 80 percent carbon dioxide in air; or

– a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30 percent by volume and the residual oxygen concentration does not exceed 2 percent by volume; or

– a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2 percent residual oxygen by volume; or

– a minimum of 2 minutes exposure to a minimum of 55 percent carbon dioxide in air; or

– a minimum of one minute exposure to 30 percent carbon dioxide in air, followed by a minimum of one minute exposure to at least 60 percent carbon dioxide in air.

ii) Requirements for effective use are as follows:

– Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.

– Gas mixtures should be humidified.

– Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

5. Bleeding

From the point of view of *animal welfare*, *animals* which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse* operator should set up a maximum stun-stick interval that ensures that no *animals* recover consciousness during bleeding. In any case the following time limits should be applied.

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Annex XXXVI (contd)

Stunning method	**Maximum stun – stick interval**
Electrical methods and non-penetrating captive bolt	20 seconds
CO_2	60 seconds (after leaving the chamber)

All *animals* should be bled out by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the *stunning* method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of view of *animal welfare*.

It should be possible for staff to observe, inspect and access the *animals* throughout the bleeding period. Any *animal* showing signs of recovering consciousness should be re-stunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the *animals* for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

~~Article 7.5.8.~~

~~**Summary analysis of stunning methods and the associated animal welfare issues**~~

[DELETE TABLE]

~~Article 7.5.9.~~

~~**Summary analysis of slaughter methods and the associated animal welfare issues**~~

[DELETE TABLE]

Article 7.5.~~10~~7.

Methods, procedures or practices unacceptable on animal welfare grounds

1) The restraining methods which work through electro-immobilisation or immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in *animals*. Those methods are not acceptable in any species.

2) The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.

3) The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning* is not acceptable in any species.

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Annex XXXVI (contd)

CHAPTER 7.6.

KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Article 7.6.1.

General principles

These recommendations are based on the premise that a decision to kill the *animals* has been made, and address the need to ensure the *welfare* of the *animals* until they are dead.

1) All personnel involved in the humane *killing* of *animals* should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience.

2) As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from *animal welfare*, aesthetics of the method of *euthanasia*, cost of the method, operator safety, biosecurity and environmental aspects.

3) Following the decision to kill the *animals*, *killing* should be carried out as quickly as possible, and normal husbandry should be maintained until the *animals* are killed.

4) The handling and movement of *animals* should be minimised and when done, it should be carried out in accordance with the recommendations described below.

5) Animal *restraint* should be sufficient to facilitate effective *killing*, and in accordance with *animal welfare* and operator safety requirements; when *restraint* is required, *killing* should follow with minimal delay.

6) When *animals* are killed for disease control purposes, methods used should result in immediate *death* or immediate loss of consciousness lasting until *death*; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive or the least aversive possible and should not cause avoidable anxiety, pain, distress or suffering in *animals*.

7) For *animal welfare* considerations, young *animals* should be killed before older *animals*; for biosecurity considerations, infected *animals* should be killed first, followed by in-contact *animals*, and then the remaining *animals*.

8) There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to *animal welfare*, operator safety and biosecurity.

9) When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on *animal welfare*, operator safety and biosecurity.

10) These general principles should also apply when *animals* need to be killed for other purposes such as after natural disasters or for culling animal populations.

Article 7.6.2.

Organisational structure

Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; *animal welfare* considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel competent in the humane *killing* of *animals* is available. Local level plans should be based on national plans and be informed by local knowledge.

Annex XXXVI (contd)

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Disease control contingency plans should address the *animal welfare* issues that may result from animal movement controls.

The operational activities should be led by an *official Veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required *animal welfare* and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved have the required competencies.

The *official Veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official Veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE *animal welfare* and animal health recommendations.

A specialist team, led by a team leader answerable to the *official Veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times.

In considering the *animal welfare* issues associated with *killing animals*, the key personnel, their responsibilities and competencies required are described in Article 7.6.3.

Article 7.6.3.

Responsibilities and competencies of the specialist team

1. Team leader

   a) Responsibilities

      i) plan overall operations on affected premises;

      ii) determine and address requirements for *animal welfare*, operator safety and biosecurity;

      iii) organise, brief and manage team of people to facilitate humane *killing* of the relevant *animals* on the premises in accordance with national regulations and these recommendations;

      iv) determine logistics required;

      v) monitor operations to ensure *animal welfare*, operator safety and biosecurity requirements are met;

      vi) report upwards on progress and problems;

      vii) provide a written report at the conclusion of the *killing*, describing the practices adopted and their effect on the *animal welfare*, operator safety and biosecurity outcomes.

   b) Competencies

      i) appreciation of normal animal husbandry practices;

      ii) appreciation of *animal welfare* and the underpinning behavioural, anatomical and physiological processes involved in the *killing* process;

      iii) skills to manage all activities on premises and deliver outcomes on time;

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iv) awareness of psychological effects on farmer, team members and general public;

v) effective communication skills;

vi) appreciation of the environmental impacts caused by their operation.

2. Veterinarian

a) Responsibilities

i) determine and supervise the implementation of the most appropriate *killing* method to ensure that *animals* are killed without avoidable pain and distress;

ii) determine and implement the additional requirements for *animal welfare*, including the order of *killing*;

iii) ensure that confirmation of the *death* of the *animals* is carried out by competent persons at appropriate times after the *killing* procedure;

iv) minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures;

v) continuously monitor *animal welfare* and biosecurity procedures;

vi) in cooperation with the leader, prepare a written report at the conclusion of the *killing*, describing the practices adopted and their effect on *animal welfare*.

b) Competencies

i) ability to assess *animal welfare*, especially the effectiveness of *stunning* and *killing* and to correct any deficiencies;

ii) ability to assess biosecurity risks.

3. Animal handlers

a) Responsibilities

i) review on-site facilities in terms of their appropriateness;

ii) design and construct temporary animal handling facilities, when required;

iii) move and restrain *animals*;

iv) continuously monitor *animal welfare* and biosecurity procedures.

b) Competencies

i) animal handling in emergency situations and in close confinement is required;

ii) an appreciation of biosecurity and containment principles.

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Annex XXXVI (contd)

4. Animal killing personnel

a) Responsibilities

Humane *killing* of the *animals* through effective *stunning* and *killing* should be ensured.

b) Competencies

i) when required by regulations, licensed to use necessary equipment;

ii) competent to use and maintain relevant equipment;

iii) competent to use techniques for the species involved;

iv) competent to assess effective *stunning* and *killing*.

5. Carcass disposal personnel

a) Responsibilities

An efficient carcass disposal (to ensure *killing* operations are not hindered) should be ensured.

b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

a) Responsibilities

i) assist when requested.

b) Competencies

i) specific knowledge of his/her *animals* and their environment.

Article 7.6.4.

Considerations in planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane *killing* of *animals*. The team leader should develop a plan for humanely *killing animals* on the premises which should include consideration of:

1) minimising handling and movement of *animals*;

2) *killing* the *animals* on the affected premises; however, there may be circumstances where the *animals* may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the recommendations in Chapter on the *slaughter* of *animals* should be followed;

3) the species, number, age and size of *animals* to be killed, and the order of *killing* them;

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4) methods of *killing* the *animals*, and their cost;

5) housing, husbandry, location of the *animals* as well as accessibility of the farm;

6) the availability and effectiveness of equipment needed for *killing* of the *animals*, as well as the time necessary to kill the required number of *animals* using such methods;

7) the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;

8) biosecurity and environmental issues;

9) the health and safety of personnel conducting the *killing*;

10) any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;

11) the presence of other nearby premises holding *animals*;

12) possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative *welfare* impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing* (choice of the *killing* sites, *killing* methods, etc.) and the measures restricting the movements of the *animals*.

Competences and skills of the personnel handling and *killing animals*.

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all *animals* are humanely and quickly killed.

~~Article 7.6.5.~~

~~**Table summarising killing methods described in Articles 7.6.6.-7.6.18.**~~

~~The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an *animal welfare* viewpoint.~~

[DELETE TABLE]

Article 7.6.~~6~~5.

Free bullet

1. Introduction

a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.

b) The most commonly used firearms for close range use are:

i) humane killers (specially manufactured/adapted single-shot weapons);

ii) shotguns (12, 16, 20, 28 bore and .410);

iii) rifles (.22 rimfire);

iv) handguns (various calibres from .32 to .45).

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Annex XXXVI (contd)

c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).

d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the *animals* (high neck shot) and to cause irreversible concussion and *death* and should only be used by properly trained and competent marksmen.

2. Requirements for effective use

a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.

b) The marksman should ensure that the *animal* is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5–50 cm for a shotgun) but the barrel should not be in contact with the head of the *animals*.

c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally, the ammunition should expand upon impact and dissipate its energy within the cranium.

d) Shot *animals* should be checked to ensure the absence of brain stem reflexes.

3. Advantages

a) Used properly, a free bullet provides a quick and effective method for *killing*.

b) It requires minimal or no *restraint* and can be use to kill from a distance by properly trained and competent marksmen.

c) It is suitable for *killing* agitated *animals* in open spaces.

4. Disadvantages

a) The method is potentially dangerous to humans and other *animals* in the area.

b) It has the potential for non-lethal wounding.

c) Destruction of brain tissue may preclude diagnosis of some *diseases*.

d) Leakage of bodily fluids may present a biosecurity risk.

e) Legal requirements may preclude or restrict use.

f) There is a limited availability of competent personnel.

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5. Conclusion

The method is suitable for cattle, sheep, goats and pigs, including large *animals* in open spaces.

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for hornless sheep and goats is on the midline.

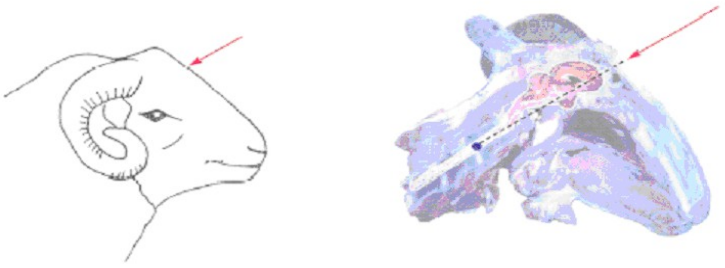

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

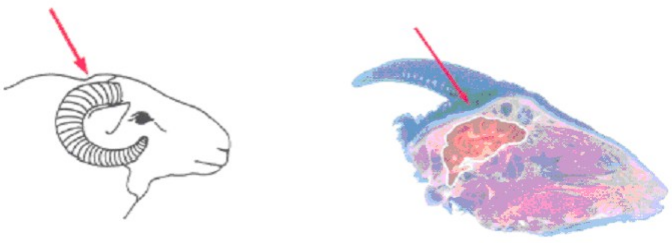

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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Annex XXXVI (contd)

Figure 4. The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Article 7.6.~~7~~6.

Penetrating captive bolt

1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the *animal*. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in *death*; however, pithing or bleeding should be performed as soon as possible after the shot to ensure the *death* of the *animal*. Shooting *poultry* species with the captive bolts results in immediate destruction of the skull and brain, causing *death*. For a detailed description on the use of this method, see Chapter 7.5. of the *Terrestrial Code*.

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.

d) *Animals* should be restrained; at a minimum, they should be penned for cartridge powered guns and in a race for compressed air guns.

e) The operator should ensure that the head of the *animal* is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).

g) To ensure the *death* of the *animal*, pithing or bleeding should be performed as soon as possible after *stunning*.

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h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

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3. Advantages

a) Mobility of cartridge powered equipment reduces the need to move *animals*.

b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.

b) Post stun convulsions may make pithing difficult and hazardous.

c) The method is difficult to apply in agitated *animals*.

d) Repeated use of a cartridge powered gun may result in over-heating.

e) Leakage of bodily fluids may present a biosecurity risk.

f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

The method is suitable for *poultry*, cattle, sheep, goats and pigs (except neonates), when followed by pithing or bleeding.

Article 7.6.~~8~~7.

Non-penetrating captive bolt

1. Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and *death* in poultry and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the *death* of the *animal*.

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.

d) *Animals* should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.

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Annex XXXVI (contd)

e) The operator should ensure that the head of the *animal* is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1–4).

g) To ensure *death* in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.

h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

a) The method induces an immediate onset of unconsciousness, and *death* in birds and neonates.

b) Mobility of equipment reduces the need to move *animals*.

4. Disadvantages

a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.

b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.

c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.

d) Post stun convulsions may make bleeding difficult and hazardous.

e) Difficult to apply in agitated *animals*; such *animals* may be sedated in advance of the *killing* procedure.

f) Repeated use of a cartridge powered gun may result in over-heating.

g) Bleeding may present a biosecurity risk.

5. Conclusions

The method is suitable for *killing* poultry, and neonate sheep, goats and pigs up to a maximum weight of 10 kg.

Article 7.6.~~9~~8.

Maceration

1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and *death* in day-old *poultry* and embryonated eggs.

2. Requirements

a) Maceration requires specialised equipment which should be kept in excellent working order.

b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

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3. Advantages

a) Procedure results in immediate *death*.

b) Large numbers can be killed quickly.

4. Disadvantages

a) Specialised equipment is required.

b) Macerated tissues may present biosecurity or human health risks.

c) The cleaning of the equipment can be a source of contamination.

5. Conclusion

The method is suitable for *killing* day-old poultry and embryonated eggs.

Article 7.6.~~10~~9.

Electrical -— two-stage application

1. Introduction

A two-stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce 'tonic/clonic' epilepsy and unconsciousness. Once the *animal* is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in *death*. The second stage (the application of low frequency current across the chest) should only be applied to unconscious *animals* to prevent unacceptable levels of pain.

2. Requirements for effective use

a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

Animal	Minimum voltage (V)	Minimum current (A)
Cattle	220	1.5
Sheep	220	1.0
Pigs over 6 weeks of age	220	1.3
Pigs less than 6 weeks of age	125	0.5

b) Appropriate protective clothing (including rubber gloves and boots) should be worn.

c) *Animals* should be restrained, at a minimum free-standing in a pen, close to an electrical supply.

d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the *animal* to allow the second application to be made.

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Annex XXXVI (contd)

e) A *stunning* current should be applied via scissor-type *stunning* tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.

f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

g) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete.

3. Advantages

a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.

b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

a) The method requires a reliable supply of electricity.

b) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.

c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).

d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).

Figure 5. Scissor-type tongs.

Article 7.6.~~11~~10.

Electrical -– single application

1. Method 1

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the *animal* and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the *animal* will not recover consciousness.

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a) Requirements for effective use

i) The stunner control device should generate a low frequency (30–60 Hz) current with a minimum voltage of 250 volts true RMS under load.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) *Animals* should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the *stunning* electrodes and the *animal* is necessary for effective use.

iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.

v) Electrodes should be cleaned regularly between *animals* and after use, to enable optimum electrical contact to be maintained.

vi) Water or saline may be necessary to improve electrical contact with sheep.

vii) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 1 stuns and kills simultaneously.

ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.

iii) A single team member only is required for the application.

iv) Non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 1 requires individual mechanical animal *restraint*.

ii) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.

iii) Method 1 requires a reliable supply of electricity.

d) Conclusion

Method 1 is suitable for calves, sheep, goats, and pigs (over one week of age).

2. Method 2

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the ‘live’ water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

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Annex XXXVI (contd)

a) Requirements for effective use

i) A mobile waterbath stunner and a short loop of processing line are required.

ii) A low frequency (50–60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.

iii) Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.

iv) The required minimum currents to stun and kill dry birds are:

– Quails – 100 mA/bird

– Chickens – 160 mA/bird

– Ducks & geese – 200 mA/bird

– Turkeys – 250 mA/bird.

A higher current is required for wet birds.

v) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 2 stuns and kills simultaneously.

ii) It is capable of processing large numbers of birds reliably and effectively.

iii) This non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 2 requires a reliable supply of electricity.

ii) Handling, inversion and shackling of birds are required.

d) Conclusion

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a *killing* method (see Article 7.6.~~17~~16.).

a) Requirements for effective use

i) The stunner control device should generate sufficient current (more than 600 mA/duck and more than 300 mA/bird) to stun.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

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iii) Birds should be restrained, at a minimum manually, close to an electrical supply.

iv) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

v) Birds should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

b) Advantages

Non-invasive technique (when combined with cervical dislocation) minimises biosecurity risk.

c) Disadvantages

i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations.

ii) The electrodes should be applied and maintained in the correct position to produce an effective stun.

iii) Birds should be individually restrained.

iv) It should be followed by a *killing* method.

d) Conclusion

Method 3 is suitable for small numbers of poultry.

Article 7.6.~~12~~11.

CO_2 / air mixture

1. Introduction

Controlled atmosphere killing is performed by exposing *animals* to a predetermined gas mixture, either by placing them in a gas-filled *container* or apparatus (Method 1) or by placing transport modules or crates containing birds in a gas tight *container* and introducing a gas mixture (Method 2) or by the gas being introduced into a poultry house (Method 3). Method 3 should be used whenever possible, as it eliminates *welfare* issues resulting from the need to manually remove live birds. Although Method 2 requires handling and crating of the birds, it benefits bird *welfare* overall in comparison with Method 1 as it reduces the risk of *death* by smothering or suffocation.

Inhalation of carbon dioxide (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, *death*. Exposure to carbon dioxide does not induce immediate loss of consciousness, therefore the aversive nature of gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase are important considerations for *animal welfare*.

2. Method 1

The *animals* are placed in a gas-filled *container* or apparatus.

a) Requirements for effective use in a *container* or apparatus

i) *Containers* or apparatus should allow the required gas concentration to be maintained and accurately measured.

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Annex XXXVI (contd)

ii) When *animals* are exposed to the gas individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

iii) *Animals* can also be introduced to low concentrations (as low concentrations are not aversive) and the concentration could be increased afterwards and the *animals* then held in the higher concentration until *death* is confirmed.

iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.

b) Advantages

i) CO_2 is readily available.

ii) Application methods are simple.

iii) The volume of gas required can be readily calculated.

iv) As the units are operated outdoor, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.

v) The system uses skilled catching teams and equipment in daily use by the industry.

vi) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

i) The need for properly designed *container* or apparatus.

ii) The aversive nature of high CO_2 concentrations.

iii) No immediate loss of consciousness.

iv) The risk of suffocation due to overcrowding.

v) Difficulty in verifying *death* while the *animals* are in the *container* or apparatus.

d) Conclusion

Method 1 is suitable for use in poultry, and neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a chamber into which gas is introduced. ~~As illustrated in the example below, a~~ A containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a single module. The chamber is fitted with gas lines and diffusers, with silencers that are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top to permit displaced air to escape when the *container* is filling with gas.

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The procedures for the operation of CGU include (a) position the *container* on level, solid, open ground; (b) connect the gas cylinder to the *container* (c) load birds into the *container* (d) shut and secure the door, (e) deliver the gas until a concentration of 45 percent by volume of carbon dioxide has been achieved at the top of the *container*, (f) allow time for the birds to become unconscious and die (g) open the door and allow gas to be dispersed in the air (h) remove the module (i) check each drawer for survivors (j) humanely kill any survivors; and (k) dispose of carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)

i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.

ii) The crates or module full of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas.

iii) Ensure the *container* door is locked and administer the gas until a minimum concentration of 45 percent carbon dioxide is achieved at the top of the crates.

iv) An appropriate gas meter should be used to ensure the appropriate concentration of carbon dioxide is achieved and maintained until it can be confirmed that the birds have been killed.

v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window that allows direct observation of birds during killing, cessation of vocalisation and convulsive wing flapping sounds, which can be listened to by standing near the *container*, can be used to determine that the birds are unconscious and that *death* is imminent. Remove the crates or modules from the *container* and leave them in the open air.

vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing indicate *death*.

vii) Any survivors should be humanely killed.

viii) Ducks and geese are resilient to the effects of carbon dioxide and therefore require a minimum of 80 percent CO_2 and a longer period of exposure to die.

b) Advantages

i) The gas is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

ii) Gradual increase in the concentration of CO_2 minimises the aversive nature of this method for inducing unconsciousness.

iii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.

iv) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

v) CO_2 is readily available.

vi) Birds are exposed to gas more uniformly and they do not smother each other when compared with Method 1.

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Annex XXXVI (contd)

vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and fork lift. However, this equipment and suitable areas with hard surfaces are usually available.

ii) The main limiting factors are speed of catching birds.

iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping sounds can be used to determine onset of *death*.

d) Conclusion

i) Method 2 is suitable for use in a wide range of poultry systems, providing there is access to *vehicles* to carry the *containers* and equipment.

ii) Birds should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the required gas concentrations, i.e. more than 40 percent CO_2. Birds are held in this atmosphere until *death* is confirmed.

iii) Method 2 is suitable for use in poultry, and neonatal sheep, goats and pigs. However, CO_2 is likely to cause a period of distress in the *animals* before they lose consciousness.

4. Method 3

The gas is introduced into a poultry house.

a) Requirements for effective use in a poultry house

i) Prior to introduction of the CO_2, the poultry house should be appropriately sealed to allow control over the gas concentration. The interval between sealing and gas administration should be kept to the minimum so as to avoid overheating.

Forced ventilation systems, where fitted, should only be switched off immediately prior to gas administration.

The main water supply to the poultry house may have to be turned off and water drained to avoid freezing and bursting of water pipes.

Feeders and water troughs should be lifted to avoid obstruction of the gas entry and prevent injury to birds.

ii) Gas delivery pipes or lancets should be positioned appropriately such that birds are not hit directly by very cold gas delivered at high pressures. It may be necessary to exclude birds from the area in front of the delivery pipes, for a distance of about 20 meters, by partitioning the house with nets, wire mesh or similarly perforated materials.

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iii) The house should be gradually filled with CO_2 so that all birds are exposed to a concentration of >40 percent until they are dead; a vaporiser may be required to prevent freezing.

iv) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

b) Advantages

i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.

ii) CO_2 is readily available.

iii) Gradual raising of CO_2 concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO_2 in some poultry houses.

ii) It is difficult to verify *death* while the birds are in the poultry house.

The extremely low temperature of liquid CO_2 entering the house and formation of solid CO_2 (dry ice) may cause concern for bird *welfare*.

d) Conclusion

Method 3 is suitable for use in poultry in closed-environment sheds. This method could be developed for killing pigs. However, CO_2 is likely to cause a period of distress in the birds before they lose consciousness.

Article 7.6.~~13~~12.

Nitrogen and/or inert gas mixed with CO2

1. Introduction

CO_2 may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is <2 percent, or <5 percent for chickens. Various mixtures of CO_2 and nitrogen or an inert gas can be administered to kill birds using Methods 1 and 2 described under Article 7.6.~~12~~11. Whole house gassing with mixtures of CO_2 and nitrogen, or an inert gas, has not been tested owing to the complex issues presented by mixing gases in large quantities. Such mixtures however do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

Pigs and poultry appear not to find low concentrations of CO_2 strongly aversive, and a mixture of nitrogen or argon with <30 percent CO_2 by volume and <2 percent O_2 by volume can be used for *killing* poultry, neonatal sheep, goats and pigs.

2. Method 1

The *animals* are placed in a gas-filled *container* or apparatus.

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Annex XXXVI (contd)

a) Requirements for effective use

i) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 and CO_2 concentrations accurately measured during the *killing* procedure.

ii) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

iii) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2 percent O_2), and held in this atmosphere until *death* is confirmed.

iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.

b) Advantages

Low concentrations of CO_2 cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

c) Disadvantages

i) A properly designed *container* or apparatus is needed.

ii) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

iii) There is no immediate loss of consciousness.

iv) Exposure times required to kill are considerable.

d) Conclusion

The method is suitable for poultry, and for neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a *container* and gas is introduced into the *container* ~~(refer to Figures under Article 7.6.12.)~~. As shown in the example below, each containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a module. The *container* or chamber is fitted with gas lines and diffusers, with silencers, which in turn are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top of the unit to permit displaced air to escape when filling the *container* with gas.

Procedures involved in the operation of CGU includes (a) position the *container* on a level, solid, open ground; (b) connect gas cylinder to the *container* (c) load a module of birds into the *container*, (d) shut and secure the door, (e) deliver the gas to the point where less than 2 percent by volume of oxygen is found at the top of the *container*, (f) allow time for the birds to become unconscious and die, (g) open the door and allow the gas to be dispersed in air, (h) remove the module, (i) check each drawer for survivors; (j) humanely kill survivors, if any; and (k) dispose carcasses appropriately.

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a) Requirements for effective use of containerised gassing units (CGU)

i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.

ii) The crates or module of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas mixture.

iii) Ensure the *container* door is locked and administer the gas mixture until <2 percent residual oxygen is achieved at the top of the crates.

iv) An appropriate gas meter should be used to ensure a concentration of oxygen <2 percent is achieved and maintained until it can be confirmed that the birds have been killed.

v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window, which allows direct observation of birds during killing, cessation of vocalisation and wing flapping sounds can be observed by standing close to the *container* and used to determine the onset of *death* in birds. Remove the crates or modules from the *container* and leave them in the open air.

vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing movements indicate *death*.

vii) Any survivors should be humanely killed.

viii) Ducks and geese do not appear to be resilient to the effects of a mixture of 20 percent carbon dioxide and 80 percent nitrogen or argon.

b) Advantages

i) The gas mixture is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

ii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.

iii) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

iv) Mixtures containing up to 20 percent carbon dioxide in argon are readily available as welding gas cylinders.

v) Birds are exposed to gas in a more uniform manner and they do not smother each other when compared with Method 1.

vi) Two CGU can be operated in tandem and throughputs of up to 4,000 chickens per hour are possible.

vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoor the gas is dispersed quickly at the end of each cycle by opening the door, improving operators' health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal *containers* can be readily cleansed and disinfected.

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Annex XXXVI (contd)

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and a fork lift. However, such equipment and suitable outdoor areas with a hard surface are usually available.

ii) The main limiting factors are speed of catching birds and availability of gas mixtures.

iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping can be used to determine the onset of *death*.

iv) CGU could be used to kill poultry on small to medium farms, e.g. up to 25 thousand birds on a single farm.

d) Conclusion

i) Method 2 is suitable for use in poultry and in neonatal sheep, goats and pigs.

ii) Method 2 is suitable for use in poultry in a wide range of poultry systems providing that these have access to *vehicles* to carry *containers* and equipment.

iii) *Animals* should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the gas mixture. A residual oxygen concentration of less than 2 percent should be achieved and maintained and birds should be held in this atmosphere until *death* is confirmed.

[DELETE THREE PICTURES]

Article 7.6.~~14~~13.

Nitrogen and/or inert gases

1. Introduction

This method involves the introduction of *animals* into a *container* or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and *death* from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 concentration accurately measured.

b) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

c) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2 percent O_2), and held in this atmosphere until *death* is confirmed.

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d) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

e) *Containers* or apparatus should not be overcrowded, and measures are needed to avoid *animals* suffocating by climbing on top of each other.

3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to *animals*.

4. Disadvantages

a) A properly designed *container* or apparatus is needed.

b) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

Article 7.6.~~15~~14.

Lethal injection

1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and *death*. In practice, barbiturates in combination with other drugs are commonly used.

2. Requirements for effective use

a) Doses and routes of administration that cause rapid loss of consciousness followed by *death* should be used.

b) Prior sedation may be necessary for some *animals*.

c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.

d) *Animals* should be restrained to allow effective administration.

e) *Animals* should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

a) The method can be used in all species.

b) *Death* can be induced smoothly.

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Annex XXXVI (contd)

4. Disadvantages

a) *Restraint* and/or sedation may be necessary prior to injection.

b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious *animals*.

c) Legal requirements and skill/training required may restrict use to veterinarians.

d) Contaminated carcasses may present a risk to other *wild animals* or domestic *animals*.

5. Conclusion

The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs and poultry.

Article 7.6.~~16~~15.

Addition of anaesthetics to feed or water

1. Introduction

An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation.

2. Requirements for effective use

a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.

b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.

c) Should be followed by *killing* (see Article 7.6.~~17~~16.) if birds are anaesthetised only.

3. Advantages

a) Handling is not required until birds are anaesthetised.

b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

a) Non-target *animals* may accidentally access the medicated feed or water when provided in an open environment.

b) Dose taken is unable to be regulated and variable results may be obtained.

c) *Animals* may reject adulterated feed or water due to illness or adverse flavour.

d) The method may need to be followed by *killing*.

e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

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5. Conclusion

The method is suitable for *killing* large numbers of poultry in houses. However, a back-up method should be available to kill birds that are anaesthetized but not killed.

Article 7.6.~~17~~16.

Cervical dislocation and decapitation

1. Cervical dislocation (manual and mechanical)

a) Introduction

Unconscious poultry may be killed by either manual or mechanical cervical dislocation (stretching the neck). This method results in *death* from cerebral anoxia due to cessation of breathing and/or blood supply to the brain.

When the number of birds to be killed is small, and other methods of *killing* are not available, conscious birds of less than 3 kilograms may be killed using cervical dislocation in such a way that the blood vessels of the neck are severed and *death* is instantaneous.

b) Requirements for effective use

i) *Killing* should be performed either by manually or mechanically stretching the neck to sever the spinal cord with consequent major damage to the spinal cord.

ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.

iii) Birds should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

i) It is a non-invasive *killing* method.

ii) It can be performed manually on small birds.

d) Disadvantages

i) Operator fatigue.

ii) The method is more difficult in larger birds.

iii) Requires trained personnel to perform humanely.

iv) Human health and safety concerns due to handling of the birds.

v) Additional stress to the *animals* from handling.

2. Decapitation

a) Introduction

Decapitation results in *death* by cerebral ischaemia using a guillotine or knife.

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Annex XXXVI (contd)

b) Requirements for effective use

The required equipment should be kept in good working order.

c) Advantages

The technique is effective and does not require monitoring.

d) Disadvantages

i) The working area is contaminated with body fluids, which increases biosecurity risks.

ii) Pain if consciousness is not lost immediately.

Article 7.6.~~18~~17.

Pithing and bleeding

1. Pithing

a) Introduction

Pithing is a method of *killing animals* which have been stunned by a penetrating captive bolt, without immediate *death*. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

b) Requirements for effective use

i) Pithing cane or rod is required.

ii) An access to the head of the *animal* and to the brain through the skull is required.

iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing immediate *death*.

d) Disadvantages

i) A delayed and/or ineffective pithing due to convulsions may occur.

ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

a) Introduction

Bleeding is a method of *killing animals* through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and *death*.

b) Requirements for effective use

i) A sharp knife is required.

ii) An access to the neck or chest of the *animal* is required.

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iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing *death* after an effective *stunning* method which does not permit pithing.

d) Disadvantages

i) A delayed and/or ineffective bleeding due to convulsions may occur.

ii) The working area is contaminated with body fluids, which increases biosecurity risks.

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Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Annex XXXVII

Original: English

January 2013

REPORT OF THE OIE *AD HOC* GROUP ON ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

Paris, 8–10 January 2013

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The OIE *ad hoc* Group on Animal Welfare and Dairy Cattle Production Systems (the *ad hoc* Group) met at the OIE Headquarters on 8–10 January 2013.

The members of the *ad hoc* Group and other participants at the meeting are listed at Annex I. The adopted agenda is at Annex II.

1. Welcome and introduction

Dr Derek Belton, Head of the Trade Department of the OIE, welcomed all members and thanked them for their agreement to work with the OIE on this important topic. Dr Belton commented to the *ad hoc* Group that the development by the OIE of animal welfare standards relevant to livestock production systems is a relatively new area of work for the OIE. Dr Belton emphasised that this topic is of great interest to OIE Members and many organisations that are associated with the OIE.

Dr Belton reminded members that in developing their recommendations the diverse conditions relevant to all 178 OIE Members should be taken into account. Dr Belton explained the procedure of adoption of OIE standards. The report of the meeting will be submitted to the OIE Animal Welfare Working Group for comments and will be presented to the Terrestrial Animal Health Standards Commission (Code Commission). The full report of the Code Commission (including the report of the *ad hoc* Group on Dairy Cattle Production Systems) will then be submitted to OIE Members for comments. Dr Mariela Varas stressed that OIE standards should be flexible, not prescriptive, and they should be science based and outcome focused. It is important to list relevant scientific references in the report as science is the unique common denominator for OIE Members. Dr Belton confirmed that the development of OIE standards is normally based on a two-year cycle and indicated that the OIE would probably reconvene the *ad hoc* Group in late 2013 to review Members and Code Commission comments on the Group's report.

Dr Gwyneth Verkerk, Chair of the *ad hoc* Group, thanked the OIE for this opportunity to work on a very important topic as animal welfare is important to the dairy industry and relevant international guidelines are needed. Dr Verkerk also noted that farmers generally accept their responsibilities for the welfare of their livestock, and are usually in the best position to ensure that.

2. Confirmation of the Terms of Reference (TOR) and discussion of working documents and other relevant documents provided by members

Documents submitted by the Members of the *ad hoc* Group were discussed.

The *ad hoc* Group noted that measurables can be based on the outcomes for the animal (outcome-based criteria) or the design of the system (resource-based or design-based criteria). The advantages and disadvantages of these two groups of criteria are well described in the report of the first meeting of the *ad hoc* Group on Animal Welfare and Livestock Production Systems, found as an annex to the report of the OIE Animal Welfare Working Group meeting of June 2008: (http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/A_WG_AW_June_2008.pdf) .

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The *ad hoc* Group agreed that outcome-based measurables may give a better indication of animal welfare because they reflect the complex interaction of several variables (e.g. experience and attitude of handlers and disease situation) that may be overlooked when relying on resource-based criteria that focus on the design of the system. They also recognised that many animal-based measurables (e.g. mortality or weight gain) are not highly specific and are frequently dependent on multiple interacting variables (e.g. environment, disease, management).

The *ad hoc* group noted that intensive production systems for rearing calves for veal had not been covered on the OIE Chapter 7.9 on Animal Welfare and Beef Cattle production systems and discussed whether these should be included in this draft. Whilst acknowledging that there were serious animal welfare issues associated with some veal calf rearing systems, the *ad hoc* group decided to concentrate on Dairy cattle and replacement calf rearing only. However they wished to draw OIE's attention to this problem.

The Terms of Reference approved can be found in Annex III.

3. Development of the draft new standard

A draft new chapter for the *Terrestrial Animal Health Code* (*Terrestrial Code*) was developed by the end of the meeting and can be found in Annex IV.

The draft new chapter is structured along the following lines:

a) definition of dairy cattle production systems for use in the new *Terrestrial Code* chapter;

b) scope of the recommendations;

c) description of existing production systems for dairy cattle production systems;

d) identification and brief description of relevant 'outcome-based measurables';

e) provisions for good animal welfare;

f) recommendations on biosecurity and animal health, environment and management of dairy cattle, with each being linked to outcome-based measurables as appropriate;

g) references.

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Annex I

OIE *AD HOC* GROUP ON ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

Paris, 8–10 January 2013

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Annex II

OIE *AD HOC* GROUP ON ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

Paris, 8–10 January 2013

Adopted agenda

1. Welcome and introduction – Dr Belton
2. Confirmation of Terms of Reference and comments from the Chair of the *ad hoc* Group
3. Introduction of members – Background and representation
4. Discussion of working documents and other relevant documents provided by the members of the *ad hoc* Group
5. Development standards
6. Review and finalise report of meeting

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Annex III

OIE *AD HOC* GROUP ON ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

Paris, 8–10 January 2013

Terms of Reference

Background

Animal welfare was first identified as a priority in the OIE Strategic Plan 2001-2005. OIE Member Countries mandated the organisation to take the lead internationally on animal welfare and, as the international reference organisation for animal health, to elaborate recommendations and guidelines covering animal welfare practices, reaffirming that animal health is a key component of animal welfare.

The standards setting procedure of the OIE

The OIE develops standards through the work of expert *ad hoc* Groups that are convened to develop draft texts for the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*). The draft texts are normally reviewed by the OIE Animal Welfare Working Group (AWWG), which provides recommendations to the OIE Terrestrial Animal Health Standards Commission (Code Commission). Following review by the Code Commission, draft texts are sent to OIE Members for comment. After two rounds of comments, a draft text may be proposed for adoption in the Terrestrial Code, in accordance with the democratic and transparent standard setting procedures of the OIE, at the World Assembly of Delegates which it's held each year in May. Reports of *ad hoc* Groups on animal welfare are normally released to the public as annexes to reports of the Code Commission. The Code Commission meets in February and September every year and its reports (in English, French and Spanish) are placed on the OIE Internet site after the meetings (normally in October and March).

Animal Welfare and livestock production systems

In May 2005, the OIE World Assembly of Delegates endorsed the proposals of the AWWG for the animal welfare priorities for 2005/2006. Among those priorities was the development of animal welfare guidelines for terrestrial animal production systems.

In April 2008, the OIE *ad hoc* group on animal welfare and livestock production systems proposed that the OIE develops guidelines based on species, with specific production sectors to be considered separately. The OIE was requested to focus on commercial scale production and particularly of products traded internationally. It was also suggested that the guidelines for a particular species should address all currently used production systems (e.g. extensive, intensive and mixed) and management procedures, in order to cover all practices used in the 178 Member Countries.

In 2009, and based on the priorities raised by the *ad hoc* group on animal welfare and livestock production systems, the OIE convened two *ad hoc* groups to draft standards on animal welfare, one for broiler chicken production systems and another one for beef cattle production systems.

In May 2011, draft chapter 7.X on animal welfare and broiler chicken production systems was submitted for adoption at the General Session. Unfortunately, this draft chapter was not adopted due to lack of consensus amongst OIE Members on several points (see comments made by OIE Members at the General Session in May 2011, Appendix 1).

As a consequence, the first meeting of the *ad hoc* Group on Animal Welfare and Dairy Cattle Production Systems was postponed to allow a clearer understanding of OIE Members expectations on production systems.

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With reference to the discussion at the General Session in May 2011 on the draft Chapter 7.X on animal welfare and broiler chicken production systems, the AWWG discussed the various positions of OIE Members on the draft text, notably in relation to the inclusion of specific measurables. Considering that it had not been possible to reconcile the positions of OIE Members to provide for adoption of the draft chapter, it was agreed that the AWWG would give priority to developing a draft text on General Principles for animal welfare and livestock production systems. In parallel, the OIE *ad hoc* Group on 'animal welfare and beef cattle production systems' reviewed the relevant draft chapter in order to address Members concerns. They made particular emphasis on the scope and definitions, as well as on the prescription given by the measurables.

In May 2012, both, "General principles for the welfare of animals in livestock production systems" and Chapter 7.9 Animal Welfare and Beef Cattle Production Systems, were adopted as Article 7.1.4.

Terms of Reference

Taking into account:

- The background history of the OIE regarding animal welfare and production systems;
- The discussion paper on the "Development of animal welfare guidelines for production systems", written by the AWWG in 2006 (Appendix 2);
- The recommendations of the OIE *ad hoc* group on animal welfare and livestock production in 2008 (Appendix 3) and
- The existing animal welfare and animal health standards in the *Terrestrial Code*, particularly Chapter 7.1 on the Guiding Principle for animal welfare http://www.oie.int/index.php?id=169&L=0&htmfile=titre_1.7.htm :

The *ad hoc* Group is asked to elaborate draft animal welfare standards for dairy cattle production for eventual inclusion in the *Terrestrial Code*. These standards should cover, *inter alia*:

- appropriate definitions (e.g. scope, commercial productions systems);
- housing;
- feeding and watering of the animals;
- environmental considerations;
- management of endemic diseases;
- prevention of major infectious diseases (biosecurity) and planning for managing disease outbreaks (including emerging diseases);
- emergency management plans (e.g. disease outbreak, failure of electrical systems, fire, etc.);
- handling facilities (on farm only – transport and slaughter are covered elsewhere in the *Terrestrial Code*);
- management practices (e.g. reproduction, disbudding, branding, milking procedures);
- breeding;
- calving;
- personnel training;
- pasture management;
- protection from predators.

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These standards must:

1. be based on science (scientific references must be provided);
2. harmonised in their structure with others on production systems (chapter 7.9);
3. use criteria that address the outcome at the animal level (animal-based).

In developing these standards, the *ad hoc* Group should review relevant resource materials, including extracts from the *Terrestrial Code*, reports from AWWG and other *ad hoc* group meetings and examples of existing practices from all five OIE Regions. A draft document is expected after the first meeting and will be submitted to the AWWG, the Code Commission and OIE Members for comments to be addressed by the *ad hoc* Group in a second meeting.

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Annex III (contd)

Appendix 1

Extract from the General Session 2011:

Animal Welfare and Broiler Chicken Production Systems

New chapter on Broiler chicken production systems (Chapter 7.X.)

Dr Thiermann noted with appreciation the extensive work of the *ad hoc* Group on Animal Welfare and Broiler Chicken Production Systems and the OIE AWWG in addressing extensive Member comments on the draft text. Dr Thiermann noted that, in response to comments of Members and animal welfare organisations, the Code Commission had made a number of amendments to the text. He noted that, once the Chapter on Animal welfare and broiler chicken production systems was adopted, it could be a useful reference for the drafting of additional chapters on animal welfare and animal production systems.

The Delegate of Costa Rica, commenting on behalf of the Member Countries of the PVC26, the Andean community and OIRSA27, thanked the OIE for its work on animal welfare and the inclusion of animal welfare in the OIE"s Fifth Strategic Plan. She raised a concern of developing countries that animal welfare could become a barrier to trade. She also noted the need for balance between animal health and welfare provisions. For broiler chicken production systems, the Delegate made several comments about the measures included in the draft chapter, noting that no scientific justification had been given and that these measures could become barriers to trade. There was no advice about tolerances for the measures, nor were there means to assess the effective application of measures. She noted that the Working Group on Animal Welfare had given priority to the period from the arrival of 1-day-old chickens to harvest and that the standards for transport were not covered in the proposed new chapter but were covered elsewhere.

The Delegate of Costa Rica did not support adoption of the draft chapter and considered that OIE Members should have the opportunity to consider the points raised in her intervention. The Delegate of Lesotho, speaking on behalf of the 52 African Members of the OIE, supported by the Delegate of Burkina Faso, recommended that the definition of backyard chicken in Article 7.X.1. be reconsidered. She stated that in West African countries backyard chickens were raised under biosecurity and could be traded between countries. The differences between intensive and semi-intensive production systems should also be reconsidered. The Delegate considered that the entire chapter was too detailed and that OIE Members could not adopt it. She recommended that the draft text be returned to the *ad hoc* Group for more work.

The Delegate of the People's Republic of China supported adoption of the chapter, because this could help to improve animal welfare and meat quality, and noted that the People's Republic of China supported the principle of animal-based criteria. He considered that the approach taken would make it feasible for Members to implement the standard.

The Delegate of the United Kingdom, speaking on behalf of the 27 Member States of the EU, acknowledged the work achieved but did not support adoption. The Delegate recommended that more general guidance on how to implement outcome-based measures and specific benchmarks be provided. Given the focus on commercial production systems, crates and slatted flooring should not be recommended on animal welfare grounds.

The Delegate of Guatemala, speaking on behalf of the OIE Members of Central America, agreed with the recommendations of African and EU Members that the chapter should be withdrawn from consideration for adoption and be studied further by the Working Group on Animal Welfare.

The President of the Commission encouraged Members to provide guidance to the OIE as there were clearly two different visions regarding this chapter, with some Members requesting the inclusion of only provisions concerning animals, while others were requesting more detailed and specific recommendations on the means to be used.

The Delegate of the United States of America considered that the chapter should be outcome focused, based on the best science available, and not too prescriptive, recognizing the variety of production systems worldwide.

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Annex III (contd)

Appendix 1 (contd)

The Delegate of Costa Rica proposed that the document of CISA28 (2008–2009) be taken into account as the countries of the region supported the approach taken in this document. The Delegate also supported the intervention of the United States of America.

The Delegate of Cuba considered that Dr Thiermann was clear in his analysis of the situation, notably recognising the significant differences between the comments made by Members. He also considered that it was in any case important to retain flexibility to provide the best opportunity for implementation by Members, so that the proposals in the new chapter being developed would be balanced and could be implemented by all countries, for the current proposal did not seem to him acceptable.

Dr Thiermann reiterated that, to develop a chapter acceptable to all Members, a common approach would need to be agreed, taking into account the wide range of production systems throughout the world. He proposed to define broiler production more clearly, to clarify which production systems, among those used globally, were the subject of the new chapter and which were not. He suggested that one way forward might be to take a similar approach to that taken in Chapter 7.5., where different methods were listed, with their relevant advantages and disadvantages.

The President withdrew the proposal for adoption of the new chapter 7.X. and asked OIE Members to provide clear guidance to the Code Commission to facilitate the provision of acceptable responses to their concerns.

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Discussion paper on the development of animal welfare guidelines for production systems (terrestrial animals)

(Developed by the OIE Animal Welfare Working Group, 2006)

Background

The OIE International Committee in May 2005 endorsed the proposals of the Animal Welfare Working Group for priorities for 2005/2006. Among those priorities was the development of animal welfare guidelines for terrestrial animal production systems.

The development of global OIE animal welfare guidelines for production systems will be challenging for a number of reasons. Worldwide, animals are raised under extremely diverse conditions ranging from intensive systems with animals kept permanently indoors, to extensive systems with little or no housing. These different systems involve very different animal welfare challenges. There are also large differences from country to country in the level of priority accorded to the welfare of food animals.

Nonetheless, because of the close link between animal welfare and animal health, guidelines designed to improve animal welfare will often lead to better animal health, productivity and food safety. Especially in cases where these relationships can be clearly demonstrated, animal welfare guidelines may be broadly acceptable to member countries.

This discussion paper sets out some of the key issues that need to be considered in developing animal welfare guidelines for production systems, and suggests next steps in this area.

Animal based and resource based criteria

Animal welfare guidelines may include (1) animal based criteria and (2) resource based criteria of animal welfare. Resource based criteria (also called design criteria or input criteria) indicate the resources that should be provided. These often specify space allowances and dimensions, ambient temperature range, humidity, condition of the litter, air quality, availability of feed and water, frequency of inspection, and biosecurity and sanitation measures. Animal based criteria (also called performance criteria or output criteria) are described/specified in terms of the animals' state. They often include such elements as survival rate, incidence of disease and injury, body condition scoring, the ability of animals to behave in certain ways, and the reaction of animals to their handlers.

Resource based criteria are widely used in animal welfare assurance programs because they are often easier to evaluate and score than animal based criteria. However, they have important limitations:

- Resource based criteria are generally derived from research carried out with specific species/breeds and production systems, and they may not be applicable to other breeds and other production systems. For example, a space allowance that minimizes crowding-related problems in light hybrid hens in battery cages may not apply to other breeds or to other housing systems.
- The welfare of animals is strongly influenced by the skill and attitude of animal handlers, and it is difficult to develop and implement resource based criteria to describe these elements.
- Resource based criteria are often created in response to well researched problems such as over-crowding and air quality, and they may not apply to new or emerging problems such as new diseases or genetic modifications of the animals.

Perhaps because of these limitations, research shows that animal production units that conform to the same resource based criteria may still have widely varying animal welfare outcomes.

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Animal based criteria are not as widely used in existing animal welfare standards but they should, in principle, be applicable to any production system. In fact animal based criteria may provide a better measure of the animal welfare outcomes because they reflect the influence of variables (e.g. experience and attitude of handlers, presence of emerging diseases) that may be missed by resource based criteria. However, many animal welfare concerns are difficult to address using animal based criteria. Examples include the capacity of the ventilation system to prevent extreme temperatures, the use of pain mitigation for surgical procedures, and the implementation of appropriate biosecurity measures.

A reasonable approach, therefore, would be for the OIE to incorporate animal based criteria in its guidelines where feasible and to supplement these with resource based criteria where there is a good scientific basis for doing so. Thus, for example, animal welfare guidelines for chickens might specify certain levels of survival and freedom from disease and injury (animal based criteria) and would also recommend requirements for ambient temperature, humidity, air quality and litter quality (resource based criteria) for birds that are kept indoors.

Clarifying the objectives of animal welfare guidelines

Animal welfare guidelines are generally designed to achieve one or more of three objectives:

1. to protect the basic health and normal functioning of animals, for example by preventing and alleviating disease, injury, malnutrition and similar harm;

2. to protect the psychological well-being of animals, for example by preventing and alleviating pain, fear, distress and discomfort;

3. to provide living conditions that are considered to be 'natural' for the species, for example by providing a social and physical environment where animals can perform key elements of their natural behaviour.

The three objectives overlap. For example, preventing injury is important for psychological well-being, and preventing pain and fear can be important for normal functioning. However, the overlap is not perfect. For example, environments that limit the spread of disease do not necessarily allow natural behaviour and vice versa.

The three objectives are based on somewhat different bodies of scientific research. The research relevant to objective 1 includes studies of survival rate, incidence of disease and injury, body condition scoring, and productivity measures. The research relevant to objective 2 includes studies of pain, fear and distress in animals, studies of ways to alleviate such states, and studies that determine the animals' own preferences and aversions. Research relevant to objective 3 includes studies of the normal (and abnormal) behaviour of animals, how these are influenced by the social and physical environment, and the strength of the animals' motivation to carry out elements of their natural behaviour.

In the past, confusion has sometimes occurred because different standards, which are all claimed to address animal welfare, have involved very different requirements. Often such differences arise because the different standards address different objectives and rely on different bodies of research. In order to avoid confusion, it is important that recommendations be clear as to the welfare objectives they are intended to address.

Standards based on objective 1, because they reinforce basic health and functioning of animals, tend to be the most aligned with the traditional objectives of animal producers and veterinarians. The cost/benefit ratio is often favourable because implementation often leads to measurable improvements in productivity (e.g. improved survival or reduced mortality due to stress and disease). Hence, these standards are likely to be the most acceptable to animal producers and in cultures where concern for the welfare of animals is relatively low. However, in cultures where the public is actively interested in and concerned about animal welfare, standards based on objective 1 are likely to be viewed as minimum standards that promote productivity rather than animal welfare per se.

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Standards based on objective 2 (alleviating pain and distress, etc.) vary in their ease of implementation and their economic implications. Some (such as handling animals in ways that do not cause distress) should be relatively easy to implement, involve little or no cost, and may produce measurable economic benefit. Others (such as requiring anaesthesia for minor surgery) may be difficult and costly to implement. The level of acceptance by producers will likely vary accordingly. In countries which accord a high priority to animals welfare, standards based on objective 2 tend to be strongly supported by the concerned public who generally see the alleviation of pain and distress as a key element of animal welfare.

Standards based on objective 3 (providing more 'natural' living conditions) can have widely varying implications. Some requirements, such as providing more natural social grouping of animals, can be achieved in confinement production systems with only small cost implications. Others may require substantial redesign of animal environments and incur higher land and labour costs. Such standards may, however, allow producers using alternative production systems to market products to consumers who support such standards.

In proposing OIE guidelines on animal production systems, one approach would be to focus principally on objective 1 because of the clear linkage with animal health and traditional veterinary priorities of this objective, and to propose the adoption of guidelines based on objectives 2 and 3 where this is feasible and appropriate. If this approach is used, however, it should be made clear that the guidelines are intended as basic guidelines designed mainly to promote the health and functioning of animals as health is the one of the key components of welfare. In cultures that place a high priority on animal welfare, the development and implementation of guidelines that more closely address animal welfare objectives 2 and 3 would be appropriate to meet societal expectations.

Clarifying the underlying science

In the past, the development of animal welfare guidelines for production systems has sometimes been hampered by a lack of clarity over the scientific literature. In some cases organizations have attempted to create guidelines without a clear review or understanding of the science. In other cases, scientific reviews are available but these lead to conflicting conclusions. Guidelines that lack a clear and transparent link to science are often criticized as reflecting the subjective views or self-interest of those (animal producers, regulators or animal welfare organizations) that produce them.

In general, then, a good first step in developing animal welfare guidelines for a given production system is to ensure that a competent review of the relevant science is in place and widely accepted. If there is no such review, or if there are significant conflicts among existing reviews, then a new review may need to be created before beginning to develop a guideline.

Recommended next steps

Given the number of strategic decisions involved in the development of guidelines for terrestrial animal production systems, the Working Group on Animal Welfare recommends that the OIE proceed as follows.

Appoint an *ad hoc* Group to consider the issues presented in this paper and prepare a Guidance Document on the development of animal welfare guidelines for terrestrial animal production systems. The *ad hoc* Group should, at a minimum, consider and report on the following:

- the various objectives of animal welfare guidelines, how these relate to animal health, and the role that the objectives should play in OIE guidelines;
- the advantages and disadvantages of animal based versus design based criteria, with examples and recommendations on how these different criteria should be addressed in developing OIE guidelines;
- the role of science in animal welfare guidelines, with recommendations on how the OIE should proceed to ensure that guidelines are clearly and transparently based on relevant science;
- a proposed strategy, including whether to approach the development of guidelines based on species (e.g. *Gallus gallus*) or production systems (e.g. caged layers);

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– recommendations on the composition of expert groups including the appropriate scientific expertise, regulatory experience and regional and cultural representation;

– priorities for development of guidelines (species, production systems).

This Guidance Document should be submitted to the Animal Welfare Working Group and, if endorsed, submitted to the OIE Code Commission and possible distribution to the OIE Delegates.

With the Guidance Document in place and endorsed by the International Committee, the OIE could proceed by appointing one or more *ad hoc* Groups to work on particular animal species or production systems. Such groups should begin with the creation of a comprehensive review of the literature where this is needed.

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Recommendations to the OIE in Developing Guidelines on Animal Welfare in Livestock Production Systems

Objectives of animal welfare guidelines

In keeping with the OIE mandate, the key objective of the OIE's animal welfare guidelines is to assure and support the essential linkage between animal health and animal welfare. In the context of this paper, animal health refers not only to freedom from diseases listed by the OIE but also to freedom from other diseases (e.g. mastitis, lameness), injuries and other conditions (e.g. malnutrition) that significantly affect the biological functioning.

In this respect, considerations relating to affective states and animal behaviour may be relevant insofar as the scientific evidence shows that they are related to animal health.

Maintaining freedom from OIE listed diseases is an important element of animal welfare and the guidelines should provide for the implementation of appropriate biosecurity measures to exclude these diseases. The guidelines should also be cross referenced to appropriate chapters in the Terrestrial Code that deal with the surveillance, reporting, control and eradication of listed diseases.

Existing OIE standards

Review of relevant existing OIE standards contributing to the objective described above will be made.

Animal based versus design based criteria

Animal based criteria (also called performance or output criteria) are described in terms of the animal's state. They include such elements as survival rate, incidence of disease and injury and body condition scoring. Many problems are multifactorial and it is therefore difficult to provide specifications (resource based criteria) for all contributing factors. The most practical solution is to monitor animal based criteria to ascertain if animal welfare problems are occurring.

Resource based criteria (also called design criteria, input criteria and engineering criteria) indicate the resources that should be provided. These specify such elements as space allowances and dimensions, ambient temperature range, humidity and condition of the litter. Resource based criteria are usually based on specific research with a particular species in a particular production system. For example, heat stress is well studied in cattle. Resource based criteria to prevent thermal stress would include specifying acceptable temperature and humidity range and rates of ventilation. However, the precise recommendations would have to be tailored for the genotype, reproductive state and history of the individual animal .Animal-based criteria such as respiratory rate and rectal temperature as measures of thermal stress, on the other hand, would be applicable across animal and genotype.

Consider the example of tail-biting in fattening pigs. Investigating the incidence and severity of tail biting is best accomplished by monitoring lesions, either by examining the pigs during the fattening period or by monitoring at the abattoir. However, correcting the problem will likely require modifying resources, for example the design of housing, stocking density, provision of material for rooting, air quality, nutrition, general hygiene and the provision of veterinary attention.

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Annex XXXVII (contd)

Annex III (contd)

Appendix 3 (contd)

List of advantages and disadvantages of animal based and resource based criteria

Animal based criteria: advantages

- Provide information on the actual state of the animal, regardless of the number of variables affecting that state
- Can be used in a range of production systems, species, genotypes etc.
- Can be quantitative or semi-quantitative (objective interpretation is possible)
- Can be used to get an appreciation of the impact of animal handling
- Post mortem monitoring may be less costly and is not stressful to the animal.

Animal based criteria: disadvantages

- May be costly to implement and stressful to the animal if based on direct intervention with individual live animals
- Can be difficult to interpret behaviour (e.g. response to chronic pain or stress)
- Range of 'normal' values and acceptable variation from normal may be difficult to establish
- Quantification may be technically difficult and require specialized training
- Identify the problem but do not indicate what corrective measures are appropriate.

Resource based criteria: advantages

- Can be easier and less costly to implement and interpret as to whether the value is within the established tolerance
- Required corrective action is evident
- Easier to calculate the cost of modifying these criteria
- Can be quantitative or semi-quantitative (objective interpretation is possible)
- Can be used in a preventative mode (e.g. biosecurity measures).

Resource based criteria: disadvantages

- Difficult to develop and implement criteria relating to handling of animals
- Criteria may not be generally applicable (they are developed on the basis of research in particular species, breeds and production systems)
- May not be available in regard to new problems (as are mainly based on research to address known problems)
- Provide only partial information on the impact on animal welfare (as many variables contribute)
- May not be well validated with respect to the overall impact on animal welfare.

The criteria for use by the OIE must be devised in a manner that provides for them to be adapted and used in a wide range of environments and circumstances, in order to be widely applicable to OIE Members.

In keeping with the OIE's proposed definition of animal welfare, the OIE guidelines should focus on animal based criteria. Animal based criteria should be supplemented with resource based criteria where these criteria are well validated scientifically as these provide some practical advantages.

The incorporation of resource based criteria is more likely to be useful when dealing with livestock production systems and livestock that are very similar, regardless of the country/region of production.

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The role of science in animal welfare guidelines

The guidelines should be based on scientific information and, to the extent that is possible, on peer-reviewed literature. However, there is a major shortage of scientific studies and publications on animal welfare from some regions, including Africa, Asia, Latin America and the Middle East, with the majority of scientific information reflecting work in the European Union, North America and Australia/New Zealand.

OIE should support the conduct of studies to generate information relevant to other regions.

Informed judgement of veterinarians and other relevant professionals is also a valid input to the development of OIE guidelines. This may be particularly relevant in addressing guidelines for livestock production systems where there is a shortage of published scientific studies.

The OIE should make clear the source and basis of its guidelines, whether this relates to professional judgement or published studies.

The OIE should undertake a review of published scientific information on

1) based and resource based criteria relevant to each guideline proposed for development (e.g. beef cattle and broiler chickens); and

2) relationship of affective states (e.g. chronic fear) and animal behaviour (e.g. nesting) to animal health.

The results of these reviews should be provided to OIE Delegates and animal welfare focal points to improve the transparency of the OIE guidelines' scientific basis.

When establishing national animal welfare policies, societal value judgements may play a large part. While science can provide useful information, ethical and social considerations may be more influential. The OIE should avoid making recommendations based on value judgements that lack a scientific basis.

Recommended strategy for the OIE

The development of guidelines based on species or sector

It is proposed that the OIE develop guidelines based on species, with specific production sectors to be considered separately as set out below. The OIE should focus on commercial scale production and particularly of products traded internationally. The guidelines for a particular species should address all currently used production systems (e.g. extensive, intensive and mixed) and management procedures (e.g. beak trimming, dehorning). The establishment of guidelines on a species by species basis is appropriate in view of the adoption of animal-based welfare criteria. Regardless of the production system, it is possible to establish animal health and welfare principles that are generally relevant to individuals of the same species.

Appropriate criteria for establishing the priority species/sectors include:

- Products that are extensively traded internationally
- Products that are internationally traded and the subject of actual or proposed animal welfare standards, measures or restrictions (government or private)
- Availability of relevant scientific information
- Likely positive impact on animal welfare of introducing standards
- Input from OIE Members and Regions regarding issues and concerns
- Relevance of one guideline for others (e.g. the OIE guideline on chickens could be used as a model to develop guidelines on ducks and turkeys).

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Annex XXXVII (contd)

Annex IV

DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

Article 7.X.1.

Definition

Dairy cattle production systems are defined as all commercial cattle production systems where the purpose of the operation includes some or all of the breeding, rearing and management of cattle intended for production of milk.

Article 7.X.2.

Scope

This chapter addresses the welfare aspects of dairy cattle production systems.

Article 7.X.3.

Commercial dairy cattle production systems

Commercial dairy cattle production systems include:

1. Housed or confined

   These are systems where cattle are in confinement and are fully dependent on humans to provide for basic animal needs such as food, shelter and water on a daily basis.

2. Pastured

   These are systems where cattle have the freedom to roam outdoors, and where the cattle have some autonomy over diet selection (through grazing), water consumption and access to shelter.

3. Combination systems

   These are systems where cattle are exposed to any combination of housing, confinement or pasture husbandry methods, either simultaneously, or varied according to changes in climatic conditions or physiological state of the cattle.

Article 7.X.4.

Criteria (or measurables) for the welfare of dairy cattle

The following outcome-based criteria, specifically animal-based criteria, can be useful indicators of *animal welfare*. The use of these indicators and their appropriate thresholds should be adapted to the different situations where dairy cattle are managed. Consideration should also be given to the design of the system. These criteria can be considered as a tool to monitor the efficiency of design and management, given that *animal welfare* will be affected by both system design and stockmanship.

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Annex IV (contd)

1. Behaviour

Certain behaviours could indicate an *animal welfare* problem. These include decreased feed intake, locomotory behaviour and posture, altered lying time, human-animal relationship, altered respiratory rate and panting, and the demonstration of stereotypic, aggressive, depressive or other abnormal behaviours (Wiepkema *et al.*, 1983; Moss, 1992; Desire *et al.*, 2002; Appleby, 2006; Mason and Latham, 2004; Lawrence, 2008; Chapinel *et al.*, 2009).

2. Morbidity rates

Morbidity rates, including for *diseases* such as mastitis and metritis, lameness, metabolic diseases, parasitic diseases, post-procedural complication and injury rates, above recognised thresholds, may be direct or indirect indicators of the *animal welfare* status of the whole *herd*. Understanding the aetiology of the *disease* or syndrome is important for detecting potential *animal welfare* problems (Blecha, 2000). Scoring systems, such as lameness scoring, can provide additional information (Sprecher *et al*., 1997).

Both clinical examination and pathology should be utilised as an indicator of *disease*, injuries and other problems that may compromise *animal welfare*. *Post-mortem* examination is useful to establish causes of *death* in cattle.

3. Mortality rates

Mortality rates, like morbidity rates, may be direct or indirect indicators of the *animal welfare* status (Moss, 1992). Depending on the production system, estimates of mortality rates can be obtained by analysing causes of *death* and the rate and temporo-spatial pattern of mortality. Mortality rates can be reported daily, monthly, annually or with reference to key husbandry activities within the production cycle.

4. Changes in milk yield, body weight and body condition

In growing *animals*, body weight gain (failure to achieve appropriate growth curve) may be an indicator of animal health and *animal welfare*.

In lactating *animals*, body condition score outside an acceptable range, significant body weight change and significant decrease in milk yield may be indicators of compromised welfare (Roche *et al.*, 2004; Roche *et al.*, 2009).

In non-lactating *animals*, including bulls, body condition score outside an acceptable range and significant body weight change may be indicators of compromised welfare.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of animal health and *animal welfare* status. Poor reproductive performance can indicate *animal welfare* problems. Examples may include:

– prolonged post-partum anoestrus,

– low conception rates,

– high abortion rates,

– high rates of dystocia,

– loss of fertility in breeding bulls.

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6. Physical appearance

Physical appearance may be an indicator of animal health and *animal welfare*, as well as the conditions of management. Attributes of physical appearance that may indicate compromised welfare include:

– presence of ectoparasites,

– abnormal coat colour, texture or hair loss,

– excessive soiling with faeces, mud or dirt (cleanliness),

– abnormal swellings and lesions,

– feet abnormalities,

– emaciation.

7. Handling responses

Improper handling can result in fear and distress in cattle. Indicators could include:

– evidence of poor human-animal relationship, such as excessive flight distance,

– negative behaviour at milking time, such as reluctance to enter to the milking parlour, kicking, vocalisation,

– percentage of *animals* striking restraints or gates,

– percentage of *animals* injured during handling, such as bruising, lacerations, broken horns and fractured legs,

– percentage of *animals* vocalising during restraint and handling,

– chute or race behaviour,

– percentage of *animals* slipping or falling.

8. Complications due to routine procedure management

Surgical and non-surgical procedures may be performed in dairy cattle for improving *animal* performance, facilitating management, and improving human safety and *animal welfare*. However, if these procedures are not performed properly, *animal welfare* can be compromised. Indicators of such problems could include:

– post procedure infection and swelling,

– body condition and weight loss,

– mortality.

Article 7.X.5.

Provisions for good animal welfare

Ensuring high welfare of dairy cattle is contingent on several management factors, including system design and stockmanship which includes responsible husbandry and appropriate care. Serious problems can arise in any system if one or more of these elements are lacking.

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.X.4. This does not exclude other measures being used where appropriate.

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1. Recommendations on system design including physical environment

When new facilities are planned or existing facilities are modified, professional advice on design in regards to animal health and welfare, should be sought (e.g. Milk Development Council, 2006).

Many aspects of the environment can impact on the health and welfare of dairy cattle. These include heat and cold, air quality, noise, etc.

a) Thermal environment

Although cattle can adapt to a wide range of thermal environments particularly if appropriate breeds are used for the anticipated conditions, sudden fluctuations in weather can cause heat or cold stress.

i) Heat stress

The risk of heat stress for cattle is influenced by environmental factors including air temperature, relative humidity and wind speed, and animal factors including breed, age, body condition, metabolic rate and coat colour and density (West, 2003; Bryant *et al.*, 2007).

Animal handlers should be aware of the risk that heat stress poses to cattle and of the thresholds in relation to heat and humidity that may require action. As conditions change, routine daily activities that require moving cattle should be amended appropriately. If the risk of heat stress reaches very high levels the *animal handlers* should institute an emergency action plan that could include provision of shade, fans, easy access to additional drinking water, and provision of cooling systems as appropriate for the local conditions (Igono *et al.*, 1987; Kendall *et al.*, 2007; Blackshaw and Blackshaw, 1994).

Outcome-based measurables: feed and water intake, behaviour, including respiratory rate and panting, morbidity rate, mortality rate, changes in milk yield.

ii) Cold stress

Protection from extreme weather conditions should be provided when these conditions are likely to create a serious risk to the welfare of cattle, particularly in neonates and young cattle and others that are physiologically compromised. This could be provided by extra bedding and natural or man-made shelters (Manninen *et al.*, 2002).

During extreme cold weather conditions, *animal handlers* should institute an emergency action plan to provide cattle with shelter, adequate feed and water.

Outcome-based measurables: mortality and morbidity rates, physical appearance, behaviour including abnormal postures, shivering and huddling, growth curve, body condition and weight loss.

b) Lighting

Confined cattle that do not have access to natural light should be provided with supplementary lighting which follows natural periodicity sufficient for their health and welfare, to facilitate natural behaviour patterns and to allow adequate inspection of the cattle (Arab *et al.*, 1995; Dahl *et al.*, 2000; Phillips *et al.*, 2000).

Outcome-based measurables: behaviour, morbidity, physical appearance, mobility.

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c) Air quality

Good air quality is an important factor for the health and welfare of cattle. It is affected by air constituents such as gases, dust and micro-organisms, and is influenced strongly by management and building design in housed systems. The air composition is influenced by the stocking density, the size of the cattle, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation is important for effective heat dissipation in cattle and preventing the build-up of effluent gases (e.g. ammonia and hydrogen sulphide) and dust in the confinement unit. Poor air quality and poor ventilation are risk factors for respiratory discomfort and *diseases*.

Outcome-based measurables: morbidity rate, behaviour, mortality rate, respiratory rate or panting, changes in weight and body condition score, growth curve.

d) Noise

Cattle are adaptable to different levels and types of noise. However, exposure of cattle to sudden and unexpected noises should be minimised where possible to prevent stress and fear reactions. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in a manner that minimises sudden and unexpected noise.

Outcome-based measurables: behaviour, changes in milk yield.

e) Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest (Baxter *et al.*, 1983; Baxter, 1992; Moberg and Mench, 2000; Bell and Huxley, 2009; O'Driscoll *et al.*, 2007). All cattle in a group should have sufficient space to lie down and rest at the same time (Kondo *et al.*, 2003).

Particular attention should be given to the provisions for calving areas. The environment in such areas (e.g. floors, bedding, temperature and hygiene) should be appropriate to ensure the welfare of calving cows and new born calves.

Floor management in housed production systems can have a significant impact on cattle welfare (Ingvartsen *et al.*, 1993; Rushen and de Passillé, 1992; Barkema *et al.*, 1999; Drissler *et al.*, 2005). Areas that compromise welfare and are not suitable for resting (e.g. places with excessive water and faecal accumulation) should not be included in the calculation of the area available for cattle to lie down.

Slopes of pens should be maintained to allow water to drain away from feed troughs and not pool excessively in the pens.

Facilities should be cleaned as conditions warrant, to ensure good hygiene and minimise disease risk.

In straw, sand or other bedding systems, the bedding should be maintained to provide cattle with a dry and comfortable place in which to lie (Bell, 2007; Bell and Huxley, 2009; Fisher *et al.*, 2003; Zdanowicz *et al.*, 2004).

The design of a standing, or cubicle, or free stall, should be such that the *animal* can stand and lie comfortably on solid surface (e.g. length, width and height should be appropriate for the size of the animal) (; Anderson, 2010; Bell 2007; Bernardi *et al.*, 2009; Cook *et al.*, 2008; Tucker *et al.*, 2003; Tucker *et al.*, 2004; Tucker *et al.*, 2009). Where possible, this design should allow for the *animal* to move its head freely as it stands up. Where individual spaces are provided for cows to rest, there should be one space per cow (Fregonesi *et al.*, 2007).

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Alleys and gates should be designed and operated to allow free movement of cattle. Slippery surfaces should be avoided (e.g. grooved concrete; metal grating, not sharp; rubber mats or deep sand) to minimise slipping and falling (Haufe *et al.*, 2009; Rushen and de Passilé, 2006).

If a housing system includes areas of slatted floor, cattle, including replacement stock, should have access to a solid lying area. The slat and gap widths should be appropriate to the hoof size of the cattle to prevent injuries (Hinterhofer *et al.*, 2006; Telezhenko *et al.*, 2007).

If cattle have to be tethered, they should, as a minimum, be able to lie down and stand up unimpeded. *Animal handlers* should be aware of the higher risks of welfare problems where cattle are tethered (Loberg *et al.*, 2004; Tucker *et al.*, 2009).

Where breeding bulls are in housing systems, care should be taken to ensure that they have sight of other cattle with sufficient space for resting and exercise. If used for natural mating, the floor should not be slatted or slippery.

Outcome-based measurables: morbidity rates (e.g. lameness, pressure sores), behaviour, changes in weight and body condition score, physical appearance (e.g. hair loss, cleanliness score), growth curve.

f) Location, construction and equipment

Farms for dairy cattle should be situated in an appropriate geographical location for the health, welfare and productivity of the cattle.

All facilities for dairy cattle should be constructed, maintained and operated to minimise the risk to the welfare of the cattle (Grandin, 1980).

Equipment for milking, handling and restraining dairy cattle should only be used in a way that minimises the risk of injury, pain or distress.

Electrified equipment (e.g. cow trainer, electrified gate) has been associated with increased incidence of welfare problems and should not be used.

Cattle in housed or pastured production systems should be offered adequate space for comfort and socialisation (Kondo *et al.*, 2003).

In all production systems, feed and water provision should allow all cattle to have unimpeded access to feed and water (DeVries and Keyserlingk, 2005; DeVries *et al.*, 2005, DeVries *et al.*, 2004; Endres *et al.*, 2005). Feeders and water providers should be clean and free of spoiled, mouldy, sour, unpalatable feed and faecal contamination.

Milking parlour, free stalls, standings, cubicles, races, chutes and pens should be free from sharp edges and protrusions to prevent injury to cattle.

Where possible, there should be a separated area to closely examine individual *animals*, which should have restraining facilities.

A hospital area for sick and injured *animals* should be provided so the *animals* can be treated away from healthy *animals*.

Hydraulic, pneumatic and manual equipment should be adjusted, as appropriate, to the size of cattle to be handled. Hydraulic and pneumatic operated restraining equipment should have pressure limiting devices to prevent injuries. Regular cleaning and maintenance of working parts is imperative to ensure the system functions properly and safe for the cattle.

Mechanical and electrical devices used in facilities should be safe for cattle.

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Dipping baths and spray races are sometimes used in dairy cattle production for ectoparasite control. Where these are used, they should be designed and operated to minimise the risk of crowding and to prevent injury and drowning.

Collecting yards (e.g. entry to the milking parlour) should be operated to minimise crowding and prevent injuries and lameness.

The loading areas and ramps should be designed to minimise stress and injuries for the *animals* and ensure the safety of the *animal handlers*, accordingly to Chapters 7.2., 7.3. and 7.4.

Outcome-based measurables: handling response, morbidity rate, mortality rate, behaviour, changes in weight and body condition score, physical appearance, lameness, growth curve.

g) Emergency plans

Where the failure of power, water and feed supply systems could compromise *animal welfare*, dairy producers should have contingency plans to cover the failure of these systems. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, access to maintenance providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and alternative feed supply.

Dairy producers should have contingency plans to cover the evacuation of animals in case of emergency (e.g. fire, flooding).

Outcome-based measurables: mortality, morbidity, behaviour, vocalization.

2. Recommendations on stockmanship and animal management

Good management and stockmanship are critical to providing an acceptable level of *animal welfare*. Personnel involved in handling and caring for dairy cattle should be competent and receive appropriate training to equip them with the necessary practical skills and knowledge of dairy cattle behaviour, health, physiological needs and welfare. There should be a sufficient number of *animal handlers* to ensure the health and welfare of the cattle.

a) Biosecurity and animal health

i) Biosecurity and disease prevention

Biosecurity means a set of measures designed to maintain a *herd* at a particular health status and to prevent the entry or spread of infectious agents.

Biosecurity plans should be designed and implemented, commensurate with the desired *herd* health status and current *disease* risk and, for OIE *listed diseases* in accordance with relevant recommendations found in the *Terrestrial Code*.

These biosecurity plans should address the control of the major sources and pathways for spread of pathogens:

– cattle,
– other domestic animals and *wildlife*,
– people,
– equipment,
– *vehicles*,
– air,
– water supply,
– feed,

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– semen.

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Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, changes in weight and body condition score, changes in milk yield.

ii) Animal health management

Animal health management means a system designed to optimise the physical and behavioural health and welfare of the dairy *herd*. It includes the prevention, treatment and control of *diseases* and conditions affecting the *herd*.

There should be an effective programme for the prevention and treatment of *diseases* and conditions, formulated in consultation with a *veterinarian*, where appropriate. This programme should include the recording of production data (e.g. number of lactating cows, animal movements in and out of the *herd*, milk yield), morbidities, mortalities, culling rate and medical treatments. It should be kept up to date by the *animal handler*. Regular monitoring of records aids management and quickly reveals problem areas for intervention.

For parasitic burdens (e.g. endoparasites, ectoparasites and protozoa), a programme should be implemented to monitor, control and treat, as appropriate.

Lameness is a problem in dairy *herds*. *Animal handlers* should monitor the state of feet and claws and maintain foot health (Chapinal *et al.*, 2009; Sprecher *et al.*, 1997).

Those responsible for the care of cattle should be aware of early specific signs of *disease* or distress (e.g. coughing, ocular discharge, changing locomotion score), and non-specific signs such as reduced feed and water intake, reduction of milk production, changes in weight and body condition, changes in behaviour or abnormal physical appearance (FAWC, UK, 1993; Ott *et al.*, 1995; Anonymous, 1997; Blecha, 2000; EU-SCAHAW, 2001; Webster, 2004; Mellor and Stafford, 2004; Millman *et al.*, 2004; OIE, 2005; Appleby, 2006; Broom, 2006; Gehring *et al.*, 2006; Fraser, 2008; Blokhuis *et al.*, 2008; Mench, 2008; Fraser, 2009; Ortiz-Pelawz *et al.*, 2008; FAWAC, Ireland; Hart, 1987; Tizard, 2008; Weary *et al.*, 2009).

Cattle at higher risk of *disease* or distress will require more frequent inspection by *animal handlers*. If *animal handlers* suspect the presence of a *disease* or are not able to correct the causes of *disease* or distress, they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers, as appropriate. In the event of an *OIE listed disease* being suspected or diagnosed, the official veterinary services should be notified (see Chapter 1.1. of the *Terrestrial Code*).

Vaccinations and other treatments administered to cattle should be undertaken by people skilled in the procedures and on the basis of veterinary or other expert advice.

Animal handlers should have experience in managing chronically ill or injured cattle, for instance in recognising and dealing with non-ambulatory cattle, especially those that have recently calved. Veterinary advice should be sought as appropriate.

Non-ambulatory cattle should have access to water at all times and be provided with feed at least once daily. They should not be transported or moved except for treatment or diagnosis. Such movements should be done carefully using methods avoiding excessive lifting.

Animal handlers should also be competent in assessing fitness to transport.

In case of chronic *disease* or injury, when treatment has been attempted and recovery deemed unlikely (e.g. cattle that are unable to stand up, unaided or refuse to eat or drink), the *animal* should be humanely killed (AABP, 1999; AVMA, 2007) and in accordance to Chapter 7.6.

Animals suffering from photosensitisation should be offered shade.

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Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, behaviour, physical appearance and changes in weight and body condition score, changes in milk yield.

iii) Emergency plans

Emergency plans should cover the management of the farm in the face of an emergency *disease outbreak*, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

b) Nutrition

The nutrient requirements of dairy cattle have been well defined. Energy, protein, mineral and vitamin content of the diet are major factors determining milk production and growth, feed efficiency, reproductive efficiency, and body condition (National Research Council, 2001).

Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets their physiological needs. Where cattle are maintained in outdoor conditions, short term exposure to climatic extremes may prevent access to nutrition that meets their daily physiological needs. In such circumstances the *animal handler* should ensure that the period of reduced nutrition is not prolonged and that extra food and water supply are provided if welfare would otherwise be compromised.

Animal handlers should have adequate knowledge of appropriate body condition scores for their cattle and should not allow body condition to go outside an acceptable range according to breed and physiological status (Roche *et al.*, 2004; Roche *et al.*, 2009).

Feedstuffs and feed ingredients should be of satisfactory quality to meet nutritional needs. Where appropriate, feed and feed ingredients should be tested for the presence of substances that would adversely impact on animal health (Binder, 2007).

The relative risk of digestive upset in cattle increases as the proportion of grain increases in the diet or if quality of silage is poor. *Animal handlers* should understand the impact of cattle size and age, weather patterns, diet composition and sudden dietary changes in respect to digestive upsets and their negative consequences (displaced abomasum, sub-acute ruminal acidosis, bloat, liver abscess, laminitis) (Enemark, 2008; Vermunt and Greenough, 1994). Where appropriate, dairy producers should consult a cattle nutritionist for advice on ration formulation and feeding programmes.

Particular attention should be paid to nutrition in the last month of pregnancy, with regards to energy balance, roughage and micronutrients, in order to minimise calving and post-calving diseases and body condition loss (Drackley, 1999; Bertoni *et al.*, 2008; Huzzey *et al.*, 2005).

Dairy producers should become familiar with potential micronutrient deficiencies or excesses for housed and pastured production systems in their respective geographical areas and use appropriately formulated supplements where necessary.

All cattle, including unweaned calves, need an adequate supply and access to palatable water that meets their physiological requirements and is free from contaminants hazardous to cattle health (Lawrence *et al.*, 2004b; Cardot *et al.*, 2008).

Outcome-based measurables: mortality rates, morbidity rates, behaviour, changes in weight and body condition score, reproductive efficiency, changes in milk yield, growth curve.

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c) Social environment

Management of cattle should take into account their social environment as it relates to *animal welfare,* particularly in housed systems (Le Neindre, 1989; Jóhannesson and Sørensen, 2000; Bøe and Færevik, 2003; Bouissou *et al.*, 2001; Kondo *et al.*, 2003; Sato *et al.*, 1993). Problem areas include: agonistic and oestrus activity, mixing of heifers and cows, feeding cattle of different size and age in the same pens, high stocking density, insufficient space at the feeder, insufficient water access and mixing of bulls.

Management of cattle in all systems should take into account the social interactions of cattle within groups. The *animal handler* should understand the dominance hierarchies that develop within different groups and focus on high risk *animals*, such as very young, very old, small or large size for cohort group, for evidence of bullying and excessive mounting behaviour. The *animal handler* should understand the risks of increased agonistic interactions between *animals*, particularly after mixing groups. Cattle that are suffering from excessive agonistic activity should be removed from the group (Bøe and Færevik, 2003; Jensen and Kyhn, 2000; von Keyserlingk *et al.*, 2008).

Animal handlers should be aware of the *animal welfare,* problems that may be caused by mixing of inappropriate groups of cattle, and provide adequate measures to minimise them (e.g. introduction of heifers in a new group, mixing of *animals* at different production stages that have different dietary needs) (Grandin, 1998; Grandin, 2003; Grandin, 2006; Kondo *et al.*, 2003).

Horned and non-horned cattle should not be mixed because of the risk of injury (Menke *et al.*, 1999).

Outcome-based measurables: behaviour (e.g. lying times), physical injuries, changes in weight and body condition score, physical appearance (e.g. cleanliness), lameness scores, changes in milk yield, morbidity rate, mortality rate, growth curve.

d) Stocking density

High stocking densities may increase injuries and have an adverse effect on growth curve, feed efficiency, and behaviour such as locomotion, resting, feeding and drinking (Martin and Bateson, 1986; Kondo *et al.*, 2003).

Stocking density should be managed such that crowding does not adversely affect normal behaviour of cattle (Bøe and Færevik, 2003). This includes the ability to lie down freely without the risk of injuries, move freely around the pen and access feed and water. Stocking density should also be managed such that weight gain and duration of time spent lying is not adversely affected by crowding (Petherick and Phillips, 2009a). If abnormal behaviour is seen, measures should be taken such as reducing stocking density.

In pastured systems, stocking density should depend on the available feed and water supply and pasture quality (Stafford and Gregory, 2008).

Outcome-based measurables: behaviour, morbidity rate, mortality rate, changes in weight and body condition score, physical appearance, changes in milk yield, parasite burden, growth curve.

e) Protection from predators

Cattle should be protected as much as possible from predators.

Outcome-based measurables: mortality rate, morbidity rate (injury rate), behaviour, physical appearance.

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f) Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a breed or subspecies for a particular location or production system (Lawrence *et al.*, 2001; Lawrence *et al.*, 2004a; Boissy and Le Neindre, 1997; Boissy *et al.*, 2007; Jensen *et al.*, 2008; Veissier *et al.*, 2008; Dillon *et al.*, 2006; Macdonald *et al.*, 2008). Examples of these include nutritional maintenance requirement, ectoparasite resistance and heat tolerance.

Individual *animals* within a breed should be selected to propagate offspring that exhibit traits beneficial to animal health and welfare by promoting robustness and longevity. These include resistance to infectious and production related *diseases*, ease of calving, fertility, body conformation and mobility, and temperament.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, reproductive efficiency, lameness, human-animal relationship, growth curve, body condition score outside an acceptable range.

g) Artificial insemination, pregnancy diagnosis and embryo transfer

Semen collection should be carried out by a trained operator in a manner that does not cause pain or distress to the bull and in accordance with Chapter 4.6.

Artificial insemination and pregnancy diagnosis should be performed by a competent operator.

Embryo transfer should be performed under an epidural or other anesthesia by a trained operator, preferably a *veterinarian* or a *veterinary para-professional*.

Outcome-based measurables: behaviour, morbidity rate, reproductive efficiency

h) Sire selection and calving management

Dystocia can be a welfare risk to dairy cattle. Heifers should not be bred before they are at stage of physical maturity sufficient to ensure the health and welfare of both dam and calf at birth. The sire has a highly heritable effect on final calf size and as such can have a significant impact on ease of calving. Sire selection for embryo implantation, insemination or natural mating, should take into account the maturity and size of the female.

Pregnant cows and heifers should be managed during pregnancy so as to achieve an appropriate body condition range for the breed. Excessive fatness increases the risk of dystocia and metabolic disorders during late pregnancy or after parturition.

Cows and heifers should be monitored when they are close to calving. *Animals* observed to be having difficulty in calving should be assisted by a competent handler as soon as possible after they are detected.

Outcome-based measurables: morbidity rate (rate of dystocia), mortality rate (cow and calf), reproductive efficiency, body condition score.

i) New born calves

Receiving adequate immunity from colostrum generally depends on the volume and quality of colostrum ingested, and how soon after birth the calf receives it.

Animal handlers should ensure that calves receive sufficient colostrum within 24 hours of birth to provide passive immunity. Where possible, calves should continue to receive colostrum or equivalent for at least 5 days after birth.

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Where new born calves need to be transported, this should be carried out according to Chapter 7.3.

Calves should be handled and moved in a manner which minimises distress and avoids pain and injury.

Outcome-based measurables: mortality rate, morbidity rate, growth curve.

j) Cow-calf separation and weaning

Different strategies to separate the calf from the cow are utilised in dairy cattle production systems. These include early separation (usually within 48 hours of birth) or a more gradual separation (leaving the calf with the cow for a longer period so it can continue to be suckled). Separation can be stressful for both cow and calf (Newberry and Swanson, 2008; Weary *et al.*, 2008).

For the purposes of this chapter, weaning means the change from a milk-based diet to a fibrous diet. This change should be done gradually and calves should be weaned only when their ruminant digestive system has developed sufficiently to enable them to maintain growth, health and welfare (Roth *et al.*, 2009).

If necessary, dairy cattle producers should seek expert advice on the most appropriate time and method of weaning for their type of cattle and production system.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, changes in weight and body condition score, growth curve.

k) Rearing of replacement stock

Young calves are at particular risk of thermal stress. Special attention should be paid to management of the thermal environment (e.g. provision of additional bedding, nutrition or protection to maintain warmth and appropriate growth).

Where possible, replacement stock should be reared in groups. Animals in groups should be of similar age and physical size (Bøe and Færevik, 2003; Jensen and Kyhn, 2000).

When in pens, each calf should have enough space to be able to turn around, rest, stand up and groom comfortably.

Replacement stock should be monitored for cross-sucking and appropriate measures taken to prevent this occurring (e.g. provision of sucking devices, use of nose guards or temporary separation).

Particular attention should be paid to the nutrition, including trace elements, of growing replacement stock to ensure good health and that they achieve an appropriate growth curve for the breed and farming objectives.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, physical appearance, changes in weight and body condition score, growth curve, reproduction efficiency.

l) Milking management

Milking should be carried out in a calm and considerate manner in order to avoid pain and distress. Special attention should be paid to the hygiene of the udder and milking equipment (Barkema *et al.*, 1999; Breen *et al.*, 2009).

A regular milking routine should be established relevant to the stage of the lactation and system (e.g. female in full lactation may need more frequent milking to relieve udder pressure). All milking cows should be checked for abnormal milk at all milking times.

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Where a milking machine is used, it should be maintained, according to the recommendations of the manufacturer, in order to minimise teat and udder damage.

Special care should be paid to *animals* being milked for the first time. If possible, they should be familiarised with the milking facility prior to giving birth.

Long waiting times before and after milking can lead to health and welfare problems (e.g. lameness, reduced time to eat). Management should ensure that waiting times are minimised.

Outcome-based measurables: morbidity rate (e.g. udder health), behaviour, changes in milk yield, physical appearance (e.g. lesions).

m) Painful husbandry procedures

Husbandry practices are routinely carried out in cattle for reasons of management, *animal welfare* and human safety. Those practices that have the potential to cause pain should be performed in such a way as to minimise any pain and stress to the *animal*.

Alternative procedures that reduce or avoid pain should be considered.

Example of such interventions include: dehorning, tail docking and identification.

i) Dehorning (including disbudding)

Dairy cattle that are naturally horned are commonly dehorned in order to reduce animal injuries and hide damage, improve human safety, reduce damage to facilities and facilitate transport and handling (Laden *et al.*, 1985; Petrie *et al.*, 1996; Singh *et al.*, 2002; Sutherland *et al.*, 2002; Stafford *et al.*, 2003; Stafford and Mellor, 2005). Where practical and appropriate for the production system, the selection of polled cattle is preferable to dehorning.

Where it is necessary to dehorn dairy cattle, producers should seek guidance from veterinary advisers as to the optimum method, use of anesthesia and analgesia, and timing for their type of cattle and production system.

Performing dehorning or disbudding at an early age, where practicable, and the use of anaesthesia or analgesia, under the supervision of a *veterinarian*, are strongly recommended.

Thermal cautery of the horn bud by a trained operator with proper equipment is the recommended method in order to minimise post-operative pain. This should be at an appropriate age before the horn bud has attached to the skull. Other methods of dehorning include: removal of the horn buds with a knife and the application of chemical paste to cauterise the horn buds. Where chemical paste is used, special attention should be paid to avoid chemical burns to other parts of the calf or to other calves.

Methods of dehorning when horn development has commenced involve the removal of the horn by cutting or sawing through the base of the horn close to the skull. Operators removing developed horns from dairy cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications (e.g. excessive bleeding, sinus infection).

ii) Tail docking

Research shows that tail docking does not improve the health and *welfare of animals*, therefore it is not recommended, as a routine procedure, to dock the tails of dairy cattle. As an alternative, trimming of tail hair should be considered where maintenance of hygiene is a problem.

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iii) Identification

Ear-tagging, ear-notching, tattooing, freeze branding and radio frequency identification devices (RFID) are preferred methods of permanently identifying dairy cattle from an *animal welfare* standpoint. In some situations however hot iron branding may be required or be the only practical method of permanent identifying dairy cattle. If cattle are branded, it should be accomplished quickly, expertly and with the proper equipment. Identification systems should be established also according to Chapter 4.1.

Outcome-based measurables: postprocedural complication rate, morbidity rate, behaviour, physical appearance, changes in weight and body condition score.

n) Inspection and handling

Dairy cattle should be inspected at intervals appropriate to the production system and the risks to the health and welfare of the cattle. In most circumstances, cattle should be inspected at least once a day. Some *animals* may benefit from more frequent inspection for example: neonatal calves (Larson *et al.*, 1998; Townsend, 1994), cows in late gestation (Boadi and Price, 1996; Mee, 2008; Odde, 1996), newly weaned calves, cattle experiencing environmental stress and those that have undergone painful husbandry procedures or veterinary treatment.

Dairy cattle identified as sick or injured should be given appropriate treatment at the first available opportunity by competent and trained *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

Recommendations on the handling of cattle are also found in Chapter 7.5. In particular handling aids that may cause pain and distress (e.g. sharp prods, electric goads) should be used only in extreme circumstances. Dairy cattle should not be prodded in sensitive areas including the udder, eyes, nose or ano-genital region.

Where dogs are used, as an aid for cattle herding, they should be properly trained. *Animal handlers* should be aware that presence of dogs can cause fear and should keep them under control at all times. The use of dogs is not appropriate in housed systems.

Cattle are adaptable to different visual environments. However, exposure of cattle to sudden or persistent movement or visual contrasts should be minimised where possible to prevent stress and fear reactions.

Electroimmobilisation should not be used.

Outcome-based measurables: human-animal relationship, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition score, changes in milk yield.

o) Personnel training

All people responsible for dairy cattle should be competent according to their responsibilities and should understand cattle husbandry, animal handling, milking routines, behaviour, biosecurity, signs of *disease*, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Competence may be gained through formal training or practical experience.

Outcome-based measurables: human-animal relationship, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition score, changes in milk yield.

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p) Disaster management

Plans should be in place to minimise and mitigate the effects of natural disasters or extreme climatic conditions, such as heat stress, drought, blizzard and flooding. Humane *killing* procedures for sick or injured cattle should be part of the emergency action plan. In times of drought, animal management decisions should be made as early as possible and these should include a consideration of reducing cattle numbers.

Reference to emergency plans can also be found in points 1 g) and 2a) iii) of Article 7.X.5.

q) Humane killing

For sick and injured cattle a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed.

The decision to kill an *animal* humanely and the procedure itself should be undertaken by a competent person.

Reasons for humane killing may include:

– severe emaciation, weak cattle that are non-ambulatory or at risk of becoming downers;

– non-ambulatory cattle that will not stand up, refuse to eat or drink, have not responded to therapy;

– rapid deterioration of a medical condition for which therapies have been unsuccessful;

– severe, debilitating pain;

– compound (open) fracture;

– spinal injury;

– central nervous system *disease*;

– multiple joint *infections* with chronic weight loss; and

– premature calves that are unlikely to survive, or calves that have debilitating congenital defect.

For a description of acceptable methods for humane *killing* of dairy cattle see Chapter 7.6.

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Annex XXXVIII

Animal Welfare Working Group: 2013 Work Programme

	Activity	Priorities of Working Group	Implementation
1	**Further work on adopted standards**	Introduction to the recommendations for animal welfare Land transport Sea transport Air transport Slaughter for human consumption Killing for disease control purposes Stray dog population control Use of animals in research and education Animal Welfare and beef cattle production systems Farmed fish transport Stunning and killing of farmed fish for human consumption Killing of farmed fish for disease control purposes	Review outcomes of General Session, including Member country submissions
		Outcome focus emphasis Comment on additional member country comments	Include in relevant written material, conference presentations, etc to reinforce OIE policy commitment. To be sent to AWWG members in October and April when TAHSC report placed on OIE internet site

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2	**Development of new standards**	• AW in broiler production systems • AW in dairy cattle production systems • Working animals • Disaster Management	Re-submitted with the Code Commission report along with AWWG comments Draft will be submitted to the Code Commission along with AWWG comments On-going: first meeting probably scheduled for 2013
3	**Standards Implementation**	• AWWG subcommittee to develop issues/options/opportunities paper	Verbal update to February Code Commission Meeting Discuss subcommittee paper at AWWG 12
4	**Wildlife**	Animal welfare problems associated with trade in wild species.	Follow up, at AWWG 12, Wilkins presentation at AWWG 11
5	**Improved animal welfare awareness within veterinary profession**	Coordinate with WVA/CVA activities	In liaison with the OIE *ad hoc* group on veterinary education
6	**Communications plan**	Working Group members to take up opportunities for publishing information articles in appropriate journals, web pages and newsletters plus conference attendance Animal Welfare and Islamic Law	Continuing (All) CVA (Rahman, Thornber, Bayvel) WVA Prague (Rahman, Fraser, Bayvel) Brazil OIE Vet Educ Conf (TBC) FAVA Taipei, 2014 Singapore (Rahman, Bayvel follow up) AVA Education Conference, 2014, Bangkok (Rahman, Bayvel follow up) Update Discussion Paper on OIE website, as required, and encourage use to promote local dialogue with religious leaders (All) World Halal Forum 2013/2014 (Rahman, Aidaros)
		Summary overview of OIE Animal Welfare achievements and current and future priorities (To be included in fact sheet)	Headquarters

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6	**Communications plan (contd)**	Working Group members to contribute to OIE Regional conferences	Continuing (All)
		To liaise with governments and international organisations re animal welfare topics at upcoming conferences and seminars including: Communication between CCs	Continuing (All)
7	**Publications**	OIE Scientific and Technical Review Series Publication "Animal Welfare Focussing on the Future"	AWWG members to meet the 2013 contribution deadline for publication in 2014
8	**Coordination with other international organisations**	IDF	Attend AWWG 12 as observer
		IMS	Attend AWWG 12 as full member
		IEC	Attend AWWG 12 as observer
		ISO Technical specification SSAFE/GFSI/GLOBAL GAP	OIE HQ to attend next meeting in February 2013 HQ liaison
		FAO	Working Animals experts meeting- (report was received, wait for release) Disaster Management- OIE HQ Liaise regarding Gateway and Podcasts
		AWIN	European Commission feedback from May 2013 Conference
		AATA/IATA/WAZA	Live Animals and Perishables Board / Time and Temperature Task Force Meetings – April 2013, Montreal

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8	**Coordination with other international organisations (contd)**	WSPA	Future collaboration between the OIE, WSPA and other international organisations in the field of disaster relief, and management and rabies
		VICH (incl. Outreach)	Liaise with Susanne Munstermann (Scientific and Technical Department), OIE Focal Point for VICH
		CIOMS/ICLAS International Guiding Principles for Biomedical Research Involving Animals	Patri Vergara will meet the DG in Paris
		EFSA	EFSA Scientific Opinion on the use of animal-based measures to assess the welfare of animals
		EC : AW and Trade Policy	Confirmed follow up to 2009 AW and International Agricultural Trade Conference: Montevideo in October 2013
9	**Working group performance**	Continued focus on priority activities, as determined by TAHSC, AAHSC and DG Continued focus on AW aspects of horizontal/cross cutting issues receiving priority OIE attention (PVS tool, Vet Legislation, Wildlife, Food Safety, One World/One Health etc)	Continue to use informal meetings and teleconferences to progress work plan between WG meetings, with circulation of teleconference action minutes to members Review performance and process issues at 2013 AWWG meeting. Prepare AWWG Teleconference September 2013 Address in AWWG 12 agenda
10	**Collaborating Centres**	Encourage recognition of appropriate international centres, in addition to Teramo, Chile/Uruguay and New Zealand /Australia Joint meeting/teleconference at AWWG meeting	Mexico application to join the CHI-URU CC. Sweden Application: no feedback since last letter ILAR Application has been submitted To be organised by HQ

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11	**Twinning**	NZ-AUS CC - University of Putra (Malaysia)	Ongoing
12	**Regional Strategies**		RAWS AFEO Regional Coordination Group 5 meeting April 2013, Bangkok Americas: Concept note has been adopted at Regional Commission in Barbados 2012 Middle East: Concept note will be submitted at Regional Commission in May 2013 Europe:Concept note being developed by Regional Commission Africa: Update to be provided at AWWG 12(Molomo)
13	**Fourth OIE Global Conference on Animal Welfare CHILE 2016**	Programme of the conference	To include the AWWG in the development of the programme
14	**Animal Welfare OIE Focal Point Training Programme**		Headquarters to inform the dates and venues of the training sessions Feedback from the trainings are expected (WG to update TAHSC)
15	**Animal Health and Welfare Fund**	Encourage financial contributions to support AW initiatives following EC, Australia and NZ examples	HQ to include in agenda for AWWG 12
16	**KL Conference**	Discuss Recommendations with particular reference to Standards Implementation and OIE Global Animal Welfare Strategy proposal	HQ to include in AWWG 12 Agenda

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Annex XXXIX

CHAPTER 8.5.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.5.1.

~~**Introduction**~~

1) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla,* and *Camelus bactrianus* with foot and mouth disease virus (FMDV).

2) The following defines the occurrence of FMDV *infection*:

   Detection in a sample from an animal listed above, of the virus, viral antigen, nucleic acid or virus-specific antibodies that are not a consequence of *vaccination* by a test as specified in the *Terrestrial Manual*.

3) The following defines the occurrence of FMDV circulation:

   Transmission of FMDV, as demonstrated by clinical signs or change in virological or serological status indicative of recent *infection*.

4) For the purposes of the *Terrestrial Code*, the *incubation period* ~~for~~ of FMD shall be 14 days.

5) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with FMDV. Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contact between them. Amongst *Camelidae* only Bactrian camels (*Camelus bactrianus*) are of sufficient susceptibility to have potential for epidemiological significance. South American camelids and dromedaries are not considered of epidemiological importance.

~~For the purposes of this chapter, ruminants include *animals* of the family of Camelidae (except *Camelus dromedarius*).~~

~~For the purposes of this chapter, a *case* is an *animal* infected with FMD virus (FMDV).~~

6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV circulation. FMDV *infection* in ruminants may persist leading to carriers. Although live FMDV can be recovered from carriers, transmission of FMDV from these carriers has not been proven, except from ~~for~~ African buffalo (*Syncerus caffer*).

7) The chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with FMDV in the absence of clinical signs.

~~The following defines the occurrence of FMDV *infection:*~~

~~1. FMDV has been isolated and identified as such from an *animal* or a product derived from that *animal*; or;~~

~~2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more *animals*, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or~~

~~3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more *animals* showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.~~

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Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.5.2.

FMD free country or zone where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.3. should be followed.

Susceptible *animals* in the FMD free country *or zone* where *vaccination* is not practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that effectively prevent the entry of the virus into the free country or *zone*~~,~~. ~~t~~Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*~~,~~ ~~T~~these measures may include a *protection zone*.

To qualify for inclusion in the existing list of FMD free countries or *zones* where *vaccination* is not practised, a Member should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that within the proposed FMD free country or *zone*:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV *infection* has been found during the past 12 months;

   c) no *vaccination* against FMD has been carried out during the past 12 months;

   ~~d) no vaccinated *animal* has been introduced since the cessation of vaccination;~~

3) supply documented evidence that for at least the past 12 months:

   a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

4) describe in detail and supply documented evidence that for at least the past 12 months these are properly implemented and supervised: ~~the boundaries and measures of a *protection zone*, if applicable.~~

   a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;

   b) the boundaries and measures of a *protection zone*, if applicable;

   c) the system for preventing the entry of the virus into the proposed FMD free country or *zone*;

   d) the control of the movement of susceptible *animals* into the proposed FMD free country or *zone* in particular if the procedure described in Articles 8.5.8., 8.5.9. and 8.5.12. are implemented;

   e) no vaccinated *animal* has been introduced during the past 12 months except in accordance with Articles 8.5.8. and 8.5.9.

The Member or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is not practiced only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

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Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

The status of a country or *zone* will not be affected by applying official emergency *vaccination* in zoological collections in the face of a clearly identifiable FMD threat, provided that the following conditions are met:

a) the zoological collection has a primary purpose to exhibit *animals* or preserve rare species and should be identified in advance, including the boundaries of the facility and be included in the country's contingency plan for FMD;

b) appropriate biosecurity measures are in place, including effective separation from other susceptible domestic populations or *wildlife*;

c) the *animals* are identifiable as belonging to the collection;

d) the vaccine used complies with the *Terrestrial Manual*;

e) *vaccination* is conducted under the supervision of the *Veterinary Authority*;

f) the zoological collection is placed under active clinical *surveillance* for at least 12 months after *vaccination*.

In the event of the application for the status of an FMD free *zone* where *vaccination* is not practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is not practised, it should be indicated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

Article 8.5.3.

FMD free country or zone where vaccination is practised

In defining a *zone* where *vaccination* is practised the principles of Chapter 4.3. should be followed.

Susceptible *animals* in the FMD free country or *zone* where *vaccination* is practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that effectively prevent the entry of the virus into the free country or *zone*~~,~~. t~~T~~aking into consideration physical or geographical barriers with any neighbouring infected country or *zone*~~,~~. ~~T~~these measures may include a *protection zone*. Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible population.

To qualify for inclusion in the list of FMD free countries or *zones* where *vaccination* is practised, a Member should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that within the proposed FMD free country or *zone*:

   a) there has been no *outbreak* of FMD during the past two years;

   b) no evidence of FMDV circulation has been found during the past 12 months;

3) supply documented evidence that:

   a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

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c) ~~routine~~ compulsory systematic *vaccination* in the target population is carried out ~~for the purpose of the prevention of FMD~~;

d) the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;

4) describe in detail and supply documented evidence that these are properly implemented and supervised ~~the boundaries and measures of a *protection zone*, if applicable.~~:

a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;

b) the boundaries and measures of a *protection zone*, if applicable;

c) the system for preventing the entry of the virus into the proposed FMD free country or *zone* (in particular if the procedure described in Article 8.5.8. is implemented);

d) the control of the movement of susceptible *animals* into the proposed FMD free country or *zone*.

The Member or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that meets the requirements of an FMD free country or *zone* where *vaccination* is practised wishes to change its status to FMD free country or *zone* where *vaccination* is not practised, it should notify the OIE in advance on the intended date of cessation of *vaccination* and apply for the new status within 24 months. The status of this country or *zone* remains unchanged until compliance with Article 8.5.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status will be suspended. If the country does not comply with requirements of Article 8.5.2., evidence should be provided within 3 months that they comply with Article 8.5.3. ~~the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred during that period.~~

In the event of the application for the status of an FMD free *zone* where *vaccination* is practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is practised, it should be indicated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

~~Article 8.5.4.~~

~~**FMD free zone where vaccination is not practised**~~

~~An FMD free *zone* where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. In defining such a *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* should be protected from the rest of the country and from neighbouring countries if they are of a different *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.~~

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~~To qualify for inclusion in the list of FMD free *zones* where vaccination is not practised, a Member should:~~

~~1. have a record of regular and prompt animal *disease* reporting;~~

~~2. send a declaration to the OIE stating that within the proposed FMD free *zone*:~~

~~a) there has been no *outbreak* of FMD during the past 12 months;~~

~~b) no evidence of FMDV *infection* has been found during the past 12 months;~~

~~c) no vaccination against FMD has been carried out during the past 12 months;~~

~~d) no vaccinated *animal* has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.10.;~~

~~3. supply documented evidence that:~~

~~a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;~~

~~b) regulatory measures for the early detection, prevention and control of FMD have been implemented;~~

~~4. describe in detail and supply documented evidence that these are properly implemented and supervised:~~

~~a) the boundaries of the proposed FMD free *zone*;~~

~~b) the boundaries and measures of a *protection zone*, if applicable;~~

~~c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).;~~

~~The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is not practised only after the submitted evidence has been accepted by the OIE.~~

~~The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.~~

~~Article 8.5.5.~~

~~**FMD free zone where vaccination is practised**~~

~~An FMD free *zone* where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* where vaccination is practised should be protected from neighbouring countries or *zones* if they are of a lesser *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.~~

~~To qualify for inclusion in the list of FMD free *zones* where vaccination is practised, a Member should:~~

~~1. have a record of regular and prompt animal *disease* reporting;~~

~~2. send a declaration to the OIE that within the proposed FMD free *zone*;~~

~~a) there has been no *outbreak* of FMD for the past two years;~~

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b) no evidence of FMDV circulation has been found during the past 12 months;

Annex XXXIX (contd)

3. supply documented evidence that:

a) *surveillance* for FMD and FMDV *infection*/circulation in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;

b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

c) routine vaccination is carried out for the purpose of the prevention of FMD;

d) the vaccine used complies with the standards described in the *Terrestrial Manual*;

4. describe in detail and supply documented evidence that these are properly implemented and supervised:

a) the boundaries of the proposed FMD free *zone*;

b) the boundaries and measures of a *protection zone*, if applicable;

c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b) c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3 b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that has a *zone* which meets the requirements of a FMD free *zone* where vaccination is practised wishes to change the status of the *zone* to FMD free *zone* where vaccination is not practised, the status of this *zone* remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred in the said *zone* during that period.

Article 8.5.4~~6~~.

FMD free compartment

An FMD free *compartment* can be established in either an FMD free country or *zone* or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible *animals* in the FMD free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member wishing to establish an FMD free *compartment* should:

1) have a record of regular and prompt animal *disease* reporting and if not FMD free, have an official control programme and a *surveillance* system for FMD in place according to Articles 8.5.~~42~~40. to 8.5.4~~7~~42. and Article 8.5.~~49~~46. that allows ~~an accurate~~ knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the FMD free *compartment* that:

a) there has been no *outbreak* of FMD during the past 12 months;

b) no evidence of FMDV *infection* has been found during the past 12 months;

c) either: ~~*vaccination* against FMD is prohibited;~~

i) no *vaccination* against FMD has been carried out during the past 12 months; no vaccinated *animal* has been introduced during the past 12 months; or

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ii) compulsory systematic *vaccination* is carried out and the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;

~~d) no *animal* vaccinated against FMD within the past 12 months is in the compartment;~~

d~~e~~) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant articles in this chapter;

e~~f~~) documented evidence shows that *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation for FMD and FMDV *infection*;

f~~g~~) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

a) the animal subpopulation in the *compartment*; ~~and~~

b) the biosecurity plan ~~for FMD and FMDV *infection*~~ and, where applicable, the *vaccination* plan, to mitigate the risks identified by the *surveillance* carried out according to point 1 of Article 8.5.4.

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no *outbreak* of FMD has occurred within a ten-kilometre radius of ~~the *zone* in which~~ the *compartment* ~~is situated,~~ during the ~~last~~ past three months.

Article 8.5.5 ~~7~~.

FMD infected country or zone

For the purposes of this chapter, when the requirements for acceptance as an FMD free country or *zone* where *vaccination* is not practised or an FMD free country or *zone* where *vaccination* is practised are not fulfilled, such country or *zone* shall be considered as FMD infected. ~~an FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.~~

~~For the purposes of this chapter, an FMD *infected zone* is a *zone* that does not fulfil the requirements to qualify as either an FMD free *zone* where vaccination is not practised or an FMD free *zone* where vaccination is practised.~~

Article 8.5.6 ~~8~~.

Establishment of a containment zone within an FMD free country or zone

In the event of limited *outbreaks* within an FMD free country or *zone*, including within a *protection zone*, with or without *vaccination*, a single *containment zone*, which includes all ~~cases~~ *outbreaks*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

For this to be achieved and for the Member to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE that:

1) the boundaries of the *containment zone* are established taking into consideration that ~~the *outbreaks* are limited based on the following factors:~~ the *outbreaks* are limited based on the following factors:

a) immediately on suspicion, animal movement control has been imposed in the country or *zone*, and effective controls on the movement of other *commodities* mentioned in this chapter are in place ~~a rapid response including notification has been made~~;

~~b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;~~

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~~c~~b) epidemiological investigation (trace-back, trace-forward) is able to demonstrate that the *outbreaks* are epidemiologically related and limited in number and geographic distribution ~~has been completed~~;

~~d) the *infection* has been confirmed~~;

~~e~~c) ~~the primary *outbreak* has been identified, and~~ investigations on the likely source of the *outbreak* have been carried out;

~~f) all *cases* have been shown to be epidemiologically linked;~~

~~g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.5.1. after the stamping-out of the last detected *case* is completed;~~

2) a *stamping-out policy*, with or without the use of emergency *vaccination,* has been applied;

3) no new *cases* have been found in the *containment zone* within a minimum of one *incubation period* as defined in Article 8.5.1. after the application of a *stamping-out policy* to the last detected *case*;

~~3.~~4) the susceptible domestic and *captive wild* animal populations within the *containment zone*~~s~~ ~~should~~ are ~~be~~ clearly identifiable as belonging to the *containment zone*;

~~4.~~5) ~~increased passive and targeted~~ *surveillance* in accordance with Articles ~~8.5.42.3 to 8.5.47~~. 8.5.41., 8.5.42. and Article 8.5.~~49~~46. in the *containment zone* and in the rest of the country or *zone* ~~has been carried out~~ is in place ~~and has not detected any evidence of FMDV *infection*~~;

~~5.~~6) animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

~~6. ongoing *surveillance* in the *containment zone* is in place.~~

The free status of the areas outside the *containment zone* ~~would be~~ is suspended ~~pending the establishment of~~ while the *containment zone* is being established. The free status of these areas may ~~could~~ be reinstated irrespective of the provisions of Article 8.5.~~9~~7., once the *containment zone* is clearly established, by complying with points 1 to 6 above. ~~The *containment zone* should be managed in such a way that it can~~ It should be demonstrated that *commodities* for *international trade* ~~can be shown to~~ have originated outside the *containment zone*.

In the event of recurrence of FMDV circulation in the *containment zone,* the approval of the *containment zone* is withdrawn.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.5.~~9~~7.

Article 8.5.7 ~~9~~.

Recovery of free status (see Figure 1)

1) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where *vaccination* is not practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where *vaccination* is not practised:

a) three months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.45. and 8.5.~~49~~46.; or

b) three months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.45. and 8.5.~~49~~46.; or

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c) six months after the last *case* or the last *vaccination* (according to the event that occurs the latest), where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated *animals*, and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.~~47~~45. and Article 8.5.~~49~~46., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population. This period can be reduced to three months if additional *surveillance* in accordance to Article 8.5.45. is carried out.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

The time periods in points 1a) to 1c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.5.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. applies.

2) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where *vaccination* is not practised, the following waiting period is required to gain the status of FMD free country or *zone* where *vaccination* is practised: 6 months after stamping out of the last *case* where a *stamping-out policy* has been applied and adoption of a continued *vaccination* policy, provided that serological *surveillance* is applied in accordance with Articles 8.5.40. to 8.5.42. and Articles 8.5.44. to 8.5.46, and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of FMDV circulation.

The country or *zone* can gain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. applies.

~~2.~~3) When an FMD *outbreak* or FMDV ~~*infection*~~ circulation occurs in an FMD free country or *zone* where *vaccination* is practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where *vaccination* is practised:

a) 6 months after the last *case* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.42. and Articles 8.5.44. to 8.5.46~~8.5.45. and Article 8.5.49~~. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or

b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency *vaccination* and serological *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.42. and Articles 8.5.44. to 8.5.46. ~~8.5.47. and Article 8.5.49~~. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

~~3.~~4) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free *compartment*, Article 8.5.~~6~~4. applies. The waiting period in point 2a) and 2b) of Article 8.5.4. can be reduced to three months provided that the entire *compartment* has been depopulated, cleansed and disinfected.

5) Members applying for the recovery of status should do so as soon as the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of this Article as soon as the *disease* has been successfully eradicated within the *containment zone*.

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Article 8.5.8 ~~10~~.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (where vaccination either is or is not practised)

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *infected zone* if transported directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1) no FMD susceptible *animal* has been introduced into the *establishment* of origin and no *animal* in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the *animals* were kept in the *establishment* of origin for at least three months prior to movement;

3) FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for at least three months prior to movement;

4) the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;

5) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *infected zone*;

6) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be derived from *animals* that have been subjected to ante- and post-mortem inspection for FMD, with favourable results within 24 hours before and after *slaughter* and treated according to point 2 of Article 8.5.~~25~~22. or Article 8.5.~~26~~23. Other products obtained from the *animals* and any products coming into contact with them should be considered infected, and treated in such a way as to destroy any residual virus in accordance with Articles 8.5.~~34~~31. to 8.5.~~41~~38.

Animals moved into a free *zone* for other purposes should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.5.~~14~~12.

Article 8.5.9~~11~~.

Direct ~~T~~ transfer ~~directly to slaughter~~ of FMD susceptible animals from a containment zone for slaughter in ~~to~~ a free zone (where vaccination either is or is not practised) ~~within a country~~

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *containment zone* if moved by mechanised transport directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1) the *containment zone* has been officially established according to the requirements in Article 8.5.~~8~~6.;

2) the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;

3) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *containment zone*;

4) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be derived from *animals* that have been subjected to ante- and post-mortem inspection for FMD, with favourable results within 24 hours before and after *slaughter* and treated according to point 2 of Article 8.5.~~25~~22. or Article 8.5.~~26~~23. Other products obtained from the *animals* and any products coming into

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contact with them should be treated in such a way as to destroy any residual virus in accordance with Articles 8.5.~~34~~31. to 8.5.~~41~~38.

Article 8.5.10.~~12~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of FMD on the day of shipment;

2) were kept since birth or for at least the past three months in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised; ~~or a FMD free *compartment*~~

3) have not been vaccinated;

4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*~~.~~;

Article 8.5.11.~~13~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of FMD on the day of shipment;

2) were kept in an FMD free country, ~~or~~ *zone or compartment* where *vaccination* is practised, since birth or for at least the past three months; ~~and~~

3) when destined to an FMD free country or *zone* where *vaccination* is not practised, have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus ~~when destined to an FMD free country or *zone* where vaccination is not practised~~;

4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*.

Article 8.5. 12.~~14~~.

Recommendations for importation from FMD infected countries or zones

For domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~the *animals*~~:

1) the *animals* showed no clinical sign of FMD on the day of shipment;

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2) prior to isolation, the *animals* were kept in the *establishment* of origin ~~since birth, or~~

   a) for ~~the past~~ 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is in force in the *exporting country*, or

   b) for ~~the past~~ 3 months, or since birth if younger than three months, if a *stamping-out policy* is not in force in the *exporting country*,

3) ~~and that~~ FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points 2 a) and b) above;

~~3~~4) the *animals* were isolated in an *establishment* or a *quarantine station* for the 30 days prior to shipment, and all *animals* in isolation were subjected to diagnostic tests (virus detection on a probang sample in ruminants or on throat swabs in pigs and serology) for evidence of FMDV *infection* with negative results on samples collected at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* or a *quarantine station* during that period; ~~or~~

4) ~~were kept in a *quarantine station* for the 30 days prior to shipment, all *animals* in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;~~

5) the *animals* were not exposed to any source of FMD *infection* during their transportation from the *establishment* or *quarantine station* to the *place of shipment*.

Article 8.5. 13.~~15~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For fresh semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

   c) were kept in an *artificial insemination centre* where none of the *animals* had a history of *infection*;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.14.~~16~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

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b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.15.~~17~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is practised;

~~c) if destined to an FMD free country or *zone* where vaccination is not practised:~~

~~i)~~c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

~~ii)~~d) had been vaccinated at least twice, with the last *vaccination* not more than 12 and not less than one month prior to collection;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

2~~3~~) the semen:

a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

b) was stored in the country of origin for a period of at least one month following collection, and during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.16~~18~~.

Recommendations for importation from FMD infected countries or zones

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

b) were kept in an ~~*establishment*~~ *artificial insemination centre* where no *animal* had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;

c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

d) had been vaccinated at least twice, with the last *vaccination* not more than 12 and not less than one month prior to collection;

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~~2. no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

~~3~~.2) the semen:

a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

b) was subjected, with negative results, to a test for FMDV ~~*infection*~~ if the donor *animal* has been vaccinated within the 12 months prior to collection;

c) was stored in the country of origin for a period of at least one month following collection, and that during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.17.~~19.~~

Recommendations for the importation of *in vivo* derived embryos of cattle

Irrespective of the FMD status of the *exporting country*, *zone* or *compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.5.18.~~20.~~

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

a) showed no clinical sign of FMD at the time of collection of the oocytes;

b) were kept for at least three months prior to ~~at the time of~~ collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.5.~~15~~13., 8.5.~~16~~14., 8.5.~~17~~15. or 8.5.~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.19.~~21~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

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1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept for at least three months prior to collection in an FMD free country, or *zones* or *compartments* where *vaccination* is practised;

   ~~c) if destined for an FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*:~~

   ~~i)~~c) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or

   ~~ii)~~d) had been vaccinated at least twice, with the last *vaccination* not less than one month and not more than 12 months prior to collection;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection~~;

2) fertilization was achieved with semen meeting the conditions referred to in Articles 8.5.~~15~~13., 8.5.~~16~~14., 8.5.~~17~~15. or 8.5.~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.20.~~22~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For fresh meat or meat products of FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

1) have been kept in the FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.;

2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

Article 8.5. 21.~~23~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For fresh meat and meat products of ruminants and pigs ~~cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

1) have been kept in the FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is practised, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.;

2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results~~.~~;

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3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, have been removed.

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~~Article 8.5.24.~~

~~**Recommendations for importation from FMD free countries or zones where vaccination is practiced**~~

~~For fresh meat or meat products of pigs and ruminants other than cattle and buffaloes~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:~~

~~1) have been kept in the FMD free country or *zone* where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;~~

~~2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.~~

Article 8.5.22.~~25~~.

Recommendations for importation from FMD infected countries or zones, where an official control programme for FMD, involving compulsory systematic vaccination ~~of cattle,~~ exists

For fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat*:

1) comes from *animals* which:

   a) have remained in the *exporting country* for at least three months prior to *slaughter*;

   b) have remained, during this period, in a part of the country where cattle and buffaloes are regularly vaccinated against FMD and where official controls are in operation;

   c) have been vaccinated at least twice with the last *vaccination* not more than 12 months and not less than one month prior to *slaughter*;

   d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;

   e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and buffaloes were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;

   f) have been slaughtered in an approved *abattoir*:

      i) which is officially designated for export;

      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

   g) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;

2) comes from deboned carcasses:

   a) from which the major lymphatic nodes have been removed;

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b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 8.5.23.~~26~~.

Recommendations for importation from FMD infected countries or zones

For meat products of ~~domestic ruminants and pigs~~ FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the entire consignment of *meat* comes from *animals* which have been slaughtered in an *approved abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;

2) the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.~~34~~31.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.5.24.~~27~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments ~~(where vaccination either is or is not practised)~~ ~~or FMD free compartments~~

For milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in an FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.

Article 8.5.25.~~28~~.

Recommendations for importation from FMD infected countries or zones where an official control programme exists

For milk, cream, milk powder and milk products

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products:

   a) originate from *establishments* ~~*herds or flocks*~~ which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.~~38~~35. and in Article 8.5.~~39~~36.;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.5.26.~~29~~.

Recommendations for importation from FMD infected countries

For blood and meat-meals from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

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Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

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Article 8.5.27.~~30~~.

Recommendations for importation from FMD infected countries

For wool, hair, bristles, raw hides and skins from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.5.~~35~~32., 8.5.~~36~~33. and 8.5.~~37~~34.;

2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Authorities can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather – e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.5.28.~~31~~.

Recommendations for importation from FMD infected countries or zones

For straw and forage

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these *commodities*:

1) are free of grossly identifiable contamination with material of animal origin;

2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ten minutes,

   b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

3) have been kept in bond for at least three months (under study) before being released for export.

Article 8.5.29.~~32~~.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

For skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from *animals* that have been killed in such a country or *zone*, or which have been imported from a country or *zone* free of FMD (where *vaccination* either is or is not practised).

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Article 8.5.30.~~33~~.

Recommendations for importation from FMD infected countries or zones

For skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 8.5.~~40~~37.

Article 8.5.31.~~34~~.

Procedures for the inactivation of the FMD virus in meat and meat products

For the inactivation of viruses present in *meat* and *meat products*, one of the following procedures should be used:

1. Canning

   Meat and *meat products* ~~is~~ are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

   Meat, previously deboned and defatted, and *meat products* shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

   After cooking, ~~it~~ they shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

   When *rigor mortis* is complete, the *meat* must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

   'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

Article 8.5.32.~~35~~.

Procedures for the inactivation of the FMD virus in wool and hair

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);

2) chemical depilation by means of slaked lime or sodium sulphide;

3) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;

4) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70°C;

5) storage of wool at ~~18°C for four weeks, or~~ 4°C for four months, 18°C for four weeks or 37°C for eight days.

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Article 8.5.33.~~36~~.

Procedures for the inactivation of the FMD virus in bristles

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1) boiling for at least one hour;

2) immersion for at least 24 hours in a 1 percent solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 8.5.34.~~37~~.

Procedures for the inactivation of the FMD virus in raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2 percent sodium carbonate.

Article 8.5.35.~~38~~.

Procedures for the inactivation of the FMD virus in milk and cream for human consumption

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1) a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or

2) if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature – short time pasteurisation [HTST]), or

3) if the milk has a pH of 7.0 or over, the HTST process applied twice.

Article 8.5.36.~~39~~.

Procedures for the inactivation of the FMD virus in milk for animal consumption

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1) the HTST process applied twice;

2) HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with dessication;

3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.5.37~~40~~.

Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the disease

For the inactivation of viruses present in skins and trophies from *wild animals* susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

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2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3) soaking, with agitation, in a 4 percent (w/v) solution of washing soda (sodium carbonate – Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours;

4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5) in the case of raw hides, salting for at least 28 days with sea salt containing 2 percent washing soda (sodium carbonate – Na_2CO_3).

Article 8.5.38.~~41~~.

Procedures for the inactivation of the FMD virus in casings of ruminants and pigs

For the inactivation of viruses present in casings of ruminants and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, ~~Aw~~ a_w< 0.80), or with phosphate supplemented ~~dry~~ salt containing 86.5 percent NaCl, 10.7 percent Na_2HPO_4 and 2.8 percent Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of greater than 12°C during this entire period.

Article 8.5.39.

OIE endorsed official control programme for FMD

The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations.*

Members may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member's *official control programme* for FMD to be endorsed by the OIE, the Member should:

1) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;

2) submit documented evidence on the capacity of the *Veterinary Services* to control FMD; this evidence can be provided by countries following the OIE PVS Pathway;

3) submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:

   a) the timeline;

   b) the performance indicators to assess the efficacy of the control measures to be implemented;

   c) submit documentation indicating that the *official control programme* for FMD is applicable to the entire country;

4) submit a dossier on the epidemiology of FMD in the country describing the following:

   a) the general epidemiology in the country highlighting the current knowledge and gaps;

   b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate virus circulation in domestic ruminants in at least one *zone* in the country;

   c) the main livestock production systems and movement patterns of FMD susceptible *animals* and their products within and into the country;

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5) submit evidence that FMD *surveillance* is in place:

   a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;

   b) have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;

6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:

   a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;

   b) detailed information on *vaccination* campaigns, in particular on:

      i) target populations for *vaccination*;

      ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

      iii) technical specification of the vaccines used and description of the licensing procedures in place;

      iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

– non-compliance with the timelines or performance indicators of the programme; or

– significant problems with the performance of the *Veterinary Services*; or

– an increase in the incidence of FMD that cannot be addressed by the programme.

Article 8.5.40.~~42~~.

Surveillance: introduction

Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Members seeking establishment, maintenance and recovery of freedom from FMD at the country, *zone* or *compartment* level, either with or without the use of *vaccination* and Members seeking endorsement of their *official control programme* for FMD, in accordance with Article 8.5.39. *Surveillance* aimed at identifying *disease* and *infection*/virus circulation should cover all the susceptible species, including *wildlife*, if applicable, within the country, *zone* or *compartment*. ~~Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without vaccination, or a *compartment*, following an *outbreak* and for the maintenance of FMD status.~~

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is ~~impossible~~ inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of ~~FMD virus (~~FMDV~~)~~ should differ significantly from an application

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designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*. *Surveillance* strategies employed for establishing and maintaining a *compartment* should also identify the prevalence, distribution and characteristics of FMD outside the *compartment* in the country or *zone. Surveillance* strategies employed in support of an OIE endorsed *official control programme* should show evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*. There is therefore considerable latitude available to Members to design and implement *surveillance* on the one hand to establish that the whole territory or part of it is free from FMDV *infection*/circulation and on the other to understand the epidemiology of FMD as part of the official FMD control programmes.

It is incumbent upon the Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are identified and managed. This should include provision of scientifically based supporting data. ~~There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that the absence of FMDV *infection* (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.~~

Surveillance for FMD should be in the form of a continuing programme. The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed to establish the prevalence of FMDV *infection* or to demonstrate the absence of FMDV *infection*/circulation may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be an appropriate strategy. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). The Member should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination*/*infection* history and production class of *animals* in the target population.

The *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection*/circulation. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* as well as *herds* which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- characterization of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- quantification of *vaccinations* performed on the affected sites;

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– sanitary protocol and history of the *establishments* with positive reactors;

– control of *animal identification* and movements;

– other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

~~*Surveillance* for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection*/circulation.~~

~~For the purposes of this chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.~~

Article 8.5.41.~~43~~.

Surveillance: ~~general conditions and methods~~ general principles

1) A *surveillance* system in accordance with Chapter 1.4. should be ~~under~~ the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples ~~from suspect *cases* of FMD~~ to a *laboratory* for FMD diagnose~~i~~s ~~as described in the *Terrestrial Manual*~~. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control.

2) The FMD *surveillance* programme should:

   a) include structured non-random *surveillance* activities as described in Article 1.4.5. with particular reference to an early warning system throughout the production, marketing and processing chain for reporting ~~suspicious~~ suspect *cases*. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect *cases* of FMD should be investigated immediately. ~~Where suspicion cannot be resolved by epidemiological and clinical investigation, s~~Samples should be taken and submitted for diagnostic testing a *laboratory*, unless the suspect *case* can be confirmed or ruled out by epidemiological and clinical investigation. ~~This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control.~~ Any *epidemiological unit* within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced;

   ~~b) implement, when relevant, regular and frequent clinical inspection and serological testing of high risk groups of *animals*, such as those adjacent to an FMD infected country or *infected zone* (for example, bordering a game park in which infected *wildlife* are present).~~

   b) implement structured population-based surveys, when appropriate, as described in Article 1.4.4.

3) The *surveillance* programme above should:

   a) identify the nature of risk factors, including the role of *wildlife*, to inform targeted *surveillance* strategies when appropriate;

   b) implement, when relevant, an appropriate combination of clinical investigation and other diagnostic procedures in high risk groups.

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~~3~~4) An effective *surveillance* system should ~~will~~ periodically identify ~~suspicious~~ suspect *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Details of the occurrence of suspect *cases* and how they were investigated and dealt with should be documented. ~~The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably~~. ~~Applications for freedom from FMDV *infection*/circulation should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with~~. This should include the results of diagnostic ~~*laboratory*~~ testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 8.5.42.~~44~~.

Surveillance: methods ~~strategies~~

~~1.~~ ~~Introduction~~

~~The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species within the country, *zone* or *compartment*.~~

~~The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.~~

~~The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection*/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.~~

~~For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.~~

~~Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of *animals* in the target population.~~

~~Irrespective of the testing system employed, *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection*/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* which may be epidemiologically linked to it.~~

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1~~2~~. Clinical surveillance

The detection of clinical signs by farmers, *veterinary para-professionals* and *veterinarians* is the foundation of an early warning system and of clinical *surveillance*. Clinical *surveillance* ~~aims at detecting clinical signs of FMD by~~ requires close physical examination of susceptible *animals*. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated~~. .~~ ~~It may~~ as it can ~~be able to~~ provide a high level of confidence of detection of *disease* if a sufficient~~ly large~~ number of clinically susceptible *animals* is examined at an appropriate frequency.

Clinical *surveillance* and ~~*laboratory*~~ diagnostic testing should ~~always~~ be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. ~~*Laboratory*~~ Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive ~~serology~~ laboratory tests. ~~Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.~~ Clinical *surveillance* may be insufficient in case of species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such cases, sero-surveillance should be used.

~~A number of issues must be considered in clinical *surveillance* for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.~~

~~Identification of clinical *cases* is fundamental to FMD *surveillance*. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such *animals*. It is essential that FMDV isolates are sent regularly to the regional reference *laboratory* for genetic and antigenic characterization.~~

~~3~~2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide materials. It is essential that FMDV isolates are sent regularly to an OIE Reference Laboratory.

Virological *surveillance* ~~using tests described in the *Terrestrial Manual* should be conducted~~ aims to:

~~a) to monitor at risk populations;~~

~~b)~~a) ~~to~~ confirm clinically suspect *cases*;

~~c~~b) ~~to~~ follow up positive serological results;

c) characterize isolates for epidemiological studies and vaccine matching;

~~d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.~~

d) monitor at risk populations.

4~~3~~. Serological surveillance

Serological *surveillance* aims at detecting antibodies against FMDV caused by *infection* or *vaccination* using either, non-structural protein (NSP) tests that detect all FMD types or type-specific tests that detect structural proteins. ~~Positive FMDV antibody test results can have four possible causes:~~

Serological *surveillance* ~~with tests described in the *Terrestrial Manual*~~ is used to:

a) estimate the prevalence or demonstrate the absence of FMDV *infection*/circulation;

b) monitor population immunity.

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~~a) natural *infection* with FMDV;~~

~~b) *vaccination* against FMD;~~

~~c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);~~

~~d) heterophile (cross) reactions.~~

~~It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).~~

~~It may be possible to use s~~Serum collected for other ~~survey~~ purposes can be used for FMD *surveillance*~~.~~, provided ~~However,~~ the principles of survey design described in this chapter are met. ~~and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.~~

~~The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.~~

The results of random or targeted serological surveys are important in providing reliable evidence ~~that FMDV *infection* is not present in a country, *zone* or *compartment*~~ of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.5.43.~~45~~.

Members applying for recognition of freedom from FMD for ~~the whole~~ a country~~, or a zone or compartment~~ where vaccination is not practised: additional surveillance procedures

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether or not *vaccination* has been used. ~~In addition to the general conditions described in the above-mentioned articles, a~~ A Member applying for recognition of FMD freedom for the country~~,~~ ~~or a~~ *zone* or *compartment* where *vaccination* is not practised should ~~provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances will be planned and implemented according to general conditions and methods in this chapter, to~~ demonstrate absence of FMDV circulation in previously vaccinated *animals* and absence of FMDV *infection* in non-vaccinated *animals*~~.~~, ~~during the preceding 12 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.~~

Article 8.5.44.~~46~~.

Members applying for recognition of freedom from FMD for ~~the whole~~ a country~~, or a zone or compartment~~ where vaccination is practised: additional surveillance procedures

~~In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of country or *zone* freedom from FMD with *vaccination* should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this chapter. Absence of clinical *disease* in the country or *zone* for the past two years should be demonstrated. Furthermore, s~~*Surveillance* should demonstrate that FMDV has not been circulating in any susceptible populations during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs ~~as described in the *Terrestrial Manual*~~. Serological surveys to demonstrate the absence of FMDV circulation should target within vaccinated populations, unvaccinated *animals* or *animals* that are less likely to show vaccine-derived antibodies to NSPs, such as young *animals* vaccinated a limited number of times, or unvaccinated *subpopulations*. ~~Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should be for at least 80 percent of the *animals* in each vaccinated population to have protective immunity. The vaccine must comply with~~

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~~the *Terrestrial Manual*.~~ Evidence to show the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity should be provided.

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In designing serosurveys to estimate population immunity, blood sample collection should be stratified by age to take account of the number of *vaccinations* the *animals* have received. The interval between last *vaccination* and sampling depends upon the intended purpose. Sampling at one or two months after *vaccination* provides information on the efficiency of the *vaccination* campaign, while sampling before or at the time of revaccination provides information on the duration of immunity. When multivalent vaccines are used, tests should be carried out to determine the antibody level at least for each serotype, if not for each antigen blended into the vaccine. The test cut-off for an acceptable level of antibody should be selected with reference to protective levels demonstrated by vaccine-challenge test results for the antigen concerned. Where the threat from circulating virus has been characterised as resulting from a field virus with significantly different antigenic properties to the vaccine virus, this should be taken into account when interpreting the protective effect of population immunity. Figures for population immunity should be quoted with reference to the total of susceptible *animals* in a given *subpopulation* and in relation to the subset of vaccinated *animals*.

~~Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.~~

~~Evidence to show the effectiveness of the vaccination programme should be provided.~~

Article 8.5.45.~~47~~.

Members re-applying for recognition of freedom from FMD for ~~the whole~~ a country, ~~or a~~ zone or compartment where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

~~In addition to the general conditions described in the above-mentioned articles, a~~A country re-applying for country, ~~or~~ *zone* or *compartment* freedom from FMD where *vaccination* is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection*/circulation. This will require serological *surveillance* incorporating, in the case of a country or a *zone* practising *vaccination*, tests able to detect antibodies to NSPs ~~as described in the *Terrestrial Manual*~~.

~~Four strategies are recognised by the OIE in a programme to eradicate FMDV *infection*/circulation following an *outbreak*:~~

~~1. *slaughter* of all clinically affected and in-contact susceptible *animals*;~~

~~2. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, with subsequent *slaughter* of vaccinated *animals*;~~

~~3. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals*;~~

~~4. vaccination used without *slaughter* of affected *animals* or subsequent *slaughter* of vaccinated *animals*.~~

~~The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.~~

Additional *surveillance* using NSP tests is required to reduce the time period from six to three months in case of *slaughter* of all clinically affected and in-contact susceptible *animals* and *vaccination* of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals* as mentioned in point 1c) of Article 8.5.7. This includes serosurveillance of all *herds* with vaccinated *animals* by sampling all vaccinated ruminants and their non-vaccinated offspring and a representative number of *animals* of other species based on an acceptable level of confidence.

~~In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active *surveillance* programme implemented according to general conditions and methods in this chapter.~~

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~~Article 8.5.48.~~

~~**OIE endorsed official control programme for FMD**~~

~~The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD.~~

~~Members may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.~~

~~For a Member's *official control programme* for FMD to be endorsed by the OIE, the Member should:~~

1. ~~submit documented evidence on the capacity of the *Veterinary Services* to control FMD; this evidence can be provided by countries following the OIE PVS Pathway;~~

2. ~~submit documentation indicating that the *official control programme* for FMD is applicable to the entire territory;~~

3. ~~have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;~~

4. ~~submit a dossier on the epidemiology of FMD in the country describing the following:~~

   a) ~~the general epidemiology in the country highlighting the current knowledge and gaps;~~

   b) ~~the measures to prevent introduction of *infection*;~~

   c) ~~the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;~~

5. ~~submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:~~

   a) ~~the timeline;~~

   b) ~~the performance indicators to assess the efficacy of the control measures to be implemented;~~

6. ~~submit evidence that FMD *surveillance*, taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter, is in place;~~

7. ~~have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual*;~~

8. ~~where vaccination is practised as a part of the *official control programme* for FMD, provide evidence (such as copies of legislation) that vaccination of selected populations is compulsory;~~

9. ~~if applicable, provide detailed information on vaccination campaigns, in particular on:~~

   a) ~~target populations for vaccination;~~

   b) ~~monitoring of vaccination coverage, including serological monitoring of population immunity;~~

   c) ~~technical specification of the vaccines used and description of the licensing procedures in place;~~

   d) ~~the proposed timeline for the transition to the use of vaccines, fully compliant with the standards and methods described in the *Terrestrial Manual*;~~

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~~10. provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.~~

~~The Member's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.~~

~~The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:~~

- ~~non-compliance with the timelines or performance indicators of the programme; or~~
- ~~significant problems with the performance of the *Veterinary Services*; or~~
- ~~an increase in the incidence of FMD that cannot be addressed by the programme.~~

Article 8.5.46.~~49~~.

The use and interpretation of serological tests (see Figure ~~1~~2)

The recommended serological tests for FMD *surveillance* are described in the *Terrestrial Manual*. Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used. Where combinations of tests are used, the overall test system performance characteristics should be known. The selection and interpretation of serological tests should be considered in the context of the epidemiological situation.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. ~~Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT).~~ Vaccinated *animals* produce antibodies mainly or entirely to the SP of the virus depending upon vaccine purity. The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. ~~Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests.~~ In unvaccinated populations, SP tests may be used to screen sera for evidence of FMDV *infection*/circulation or to detect the introduction of vaccinated *animals*. In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the *vaccination* and can help to identify *infection* since vaccinated-and-infected *animals* may have higher SP antibody titres than vaccinated-only *animals*.

~~In contrast to SP tests,~~ NSP tests can detect antibodies due to *infection*/circulation for ~~to~~ all serotypes of FMD virus regardless of the *vaccination* status of the *animals* provided the vaccines comply with the standards of the *Terrestrial Manual* insofar as purity is concerned. However, although ~~*a*~~*Animals* vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, ~~but in some,~~ the ~~titre~~ levels may be lower than ~~that~~ those found in infected *animals* that have not been vaccinated. To ensure that all *animals* that had contact with the FMDV have seroconverted it is recommended to take samples for NSP antibody testing not earlier than 30 days after the last case and in any case not earlier than 30 days after the last *vaccination*.

~~Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.~~

~~Serological testing is a suitable tool for FMD *surveillance*. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection*/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical *surveillance*. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results. In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However,~~

~~NSP antibody tests should be used to monitor for FMDV *infection*/circulation. NSP-ELISAs may be used for screening sera for evidence of *infection*/circulation irrespective of the vaccination status of the *animal*.~~

Positive FMDV antibody test results can have five possible causes:

a) *infection* with FMDV;

b) *vaccination* against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for longer periods);

d) non-specific reactivity of the serum;

e) lack of specificity of the diagnostic tests used.

Procedure in case of positive test results

All seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimize false positive test reactors. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The number and strength of sero reactors should be taken into account.

All *herds* with ~~seropositive~~ at least one *laboratory* confirmed reactor~~s~~ should be investigated immediately. ~~Epidemiological and supplementary *laboratory* investigation results should document the status of FMDV *infection*/circulation for each positive *herd*.~~ The investigation should examine all evidence, including the results of virological tests that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to virus circulation and should document the status of FMDV *infection*/circulation for each positive *herd*. Epidemiological investigation should be continued in parallel.

Clustering of seropositive reactions should be investigated as it may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of *infection*/circulation. As clustering may signal *infection*/circulation, the investigation of all instances must be incorporated in the survey design.

Paired serology can be used to identify virus circulation by demonstrating an increase in the number of seropositive *animals* or an increase in antibody titre at the second sampling.

The investigation should include the reactor *animal(s)*, susceptible *animals* of the same *epidemiological unit* and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)*. The *animals* sampled should remain in the holding pending test results, should be clearly identifiable, accessible and should not be vaccinated during the investigations, so that they can be retested after an adequate period of time. Following clinical examination, a second sample should be taken from the *animals* tested in the initial survey with emphasis on *animals* in direct contact with the reactor(s) after an adequate interval of time has lapsed. If the *animals* are not individually identified, a new serological survey should be carried out in the holding(s) after an adequate period of time, repeating the application of the primary survey design. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

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Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and preferably belonging to the same species resident within the initial positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological* unit under investigation for at least two *incubation periods* and should remain serologically negative if virus is not circulating.

~~Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.~~

~~Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.~~

~~1.~~ ~~The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination country or, zone where vaccination is not practised~~

~~Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor *animal* at hand, of susceptible *animals* of the same *epidemiological unit* and of susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal*. If the follow-up investigations provide no evidence FMDV infection, the reactor *animal* shall be classified as FMD negative. In all other cases including the absence of such follow-up investigations, the reactor *animal* should be classified as FMD positive.~~

If circulation is proved then the *outbreak* is declared.

In the absence of FMDV circulation, an *outbreak* can be ruled out, but the significance of FMD positive *animals* is difficult to classify. Such findings can be an indication of acute *infection* followed by recovery or by the development of the carrier state, in ruminants, or due to non-specific reaction or lack of specificity of the diagnostic tests used. Antibodies to NSP may be induced by repeat *vaccination* with vaccines that do not comply with the requirements for purity. However the use of such vaccines is not permissible for countries, *zones* or *compartments* applying for an official status.

In the case of a vaccinated *herd* in a country, *zone* or *compartment* trying to establish or re-establish the status of an FMD free country, *zone* or *compartment* where *vaccination* is practised, the follow-up investigations may be considered completed where the *herd* can be declared free of FMDV circulation. In the case of a number of FMD positive *animals* at a level above the expected number of non-specific test system findings, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)* should be investigated.

In all other cases, when a small number of FMD positive *animals* are found, at a level consistent with the expected number of non-specific test system findings, it is recommended that such reactor *animals* should be slaughtered, and then the *herd* declared free of FMDV *infection*. In the case of a number of FMD positive *animals* at a level above the expected number of non-specific test system findings, it is recommended that the *herd* should be slaughtered and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)* should be investigated.

~~2.~~ ~~The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free country or zone where vaccination is practised status with vaccination~~

~~In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on FMD vaccinated populations.~~

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~~The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.~~

~~It is suggested that in the primary sampling units where at least one *animal* reacts positive to the NSP test, the following strategy(ies) should be applied:~~

~~a) Following clinical examination, a second serum sample should be taken from the *animals* tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. The number of *animals* with antibodies against NSP in the population at the time of retest should be statistically either equal to or less than that observed in the initial test if virus is not circulating.~~

~~The *animals* sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all *animals* tested are individually identified. These *animals* should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.~~

~~b) Following clinical examination, serum samples should be collected from representative numbers of susceptible *animals* that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.~~

~~c) Following clinical examination, epidemiologically linked *herds* should be serologically tested and satisfactory results should be achieved if virus is not circulating.~~

~~d) Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence.~~

~~*Laboratory* results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:~~

- ~~characterization of the existing production systems;~~
- ~~results of clinical *surveillance* of the suspects and their cohorts;~~
- ~~quantification of *vaccinations* performed on the affected sites;~~
- ~~sanitary protocol and history of the *establishments* with positive reactors;~~
- ~~control of *animal identification* and movements;~~
- ~~other parameters of regional significance in historic FMDV transmission.~~

~~The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.~~

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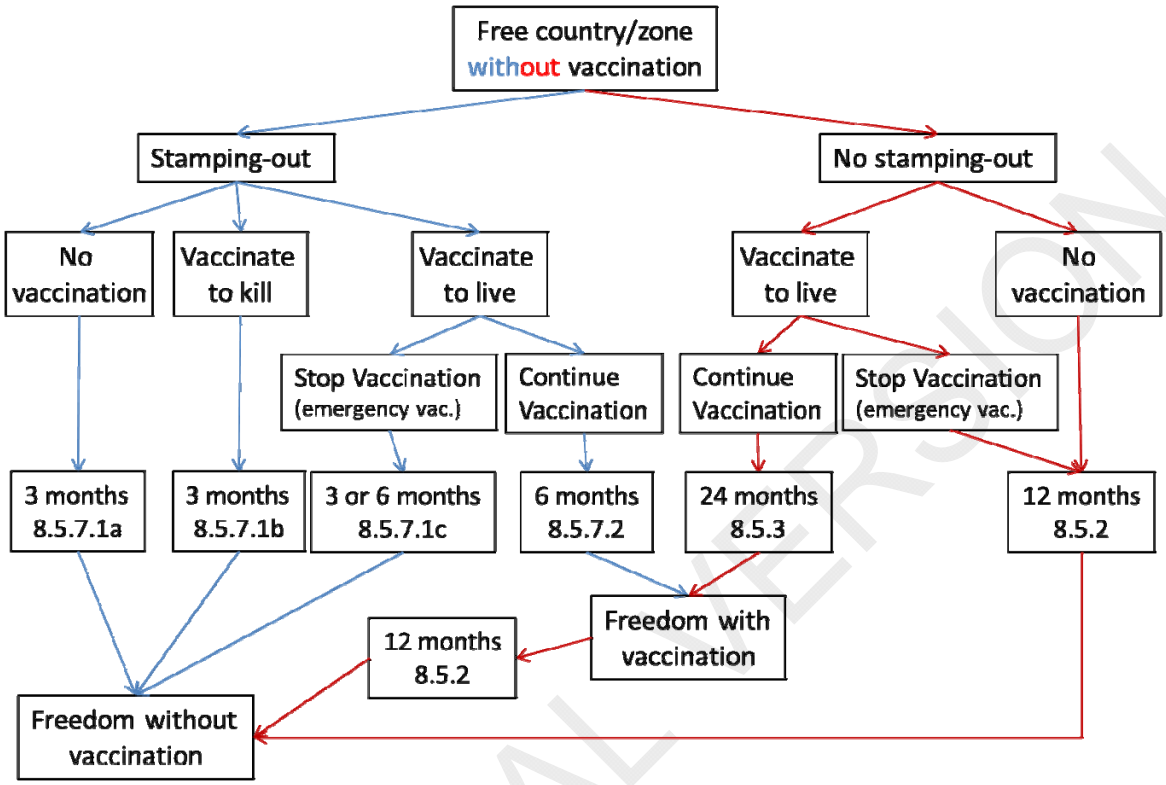
Annex XXXIX (contd)

Figure 1: Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status



**Waiting periods are minima depending upon outcome of surveillance specified in respective Articles*

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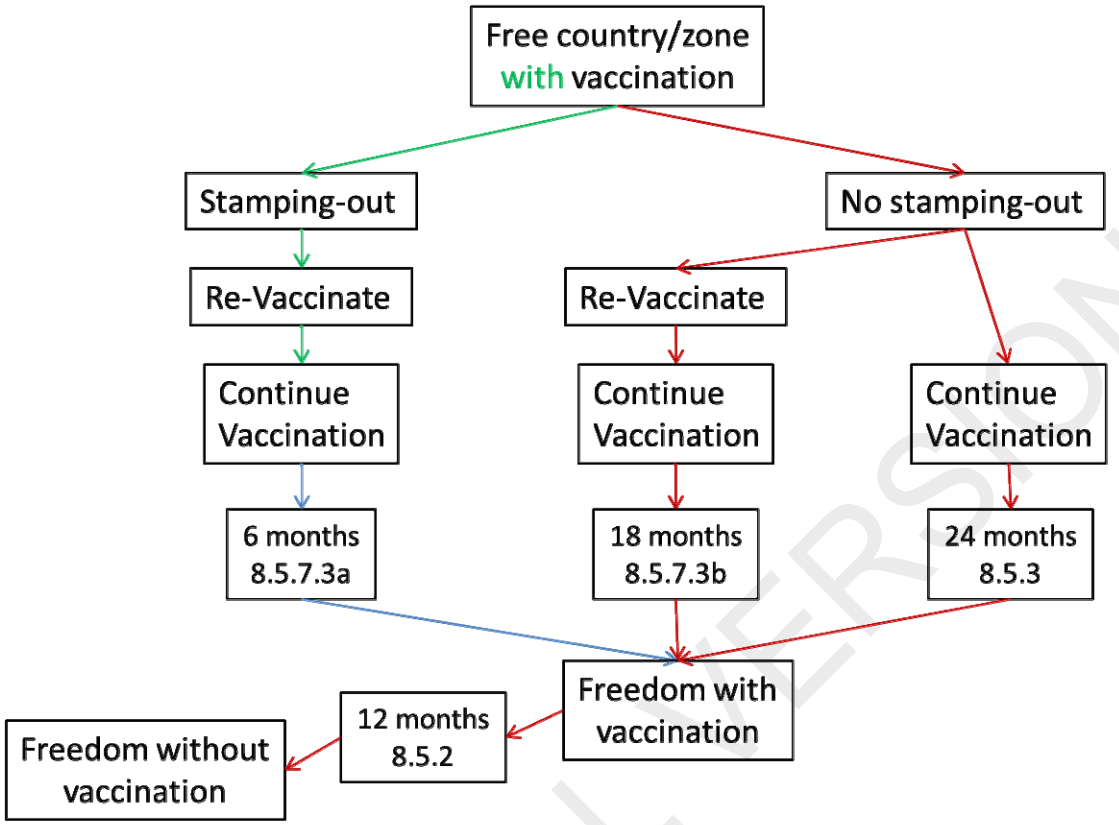

**Waiting periods are minima depending upon outcome of surveillance specified in respective Articles*

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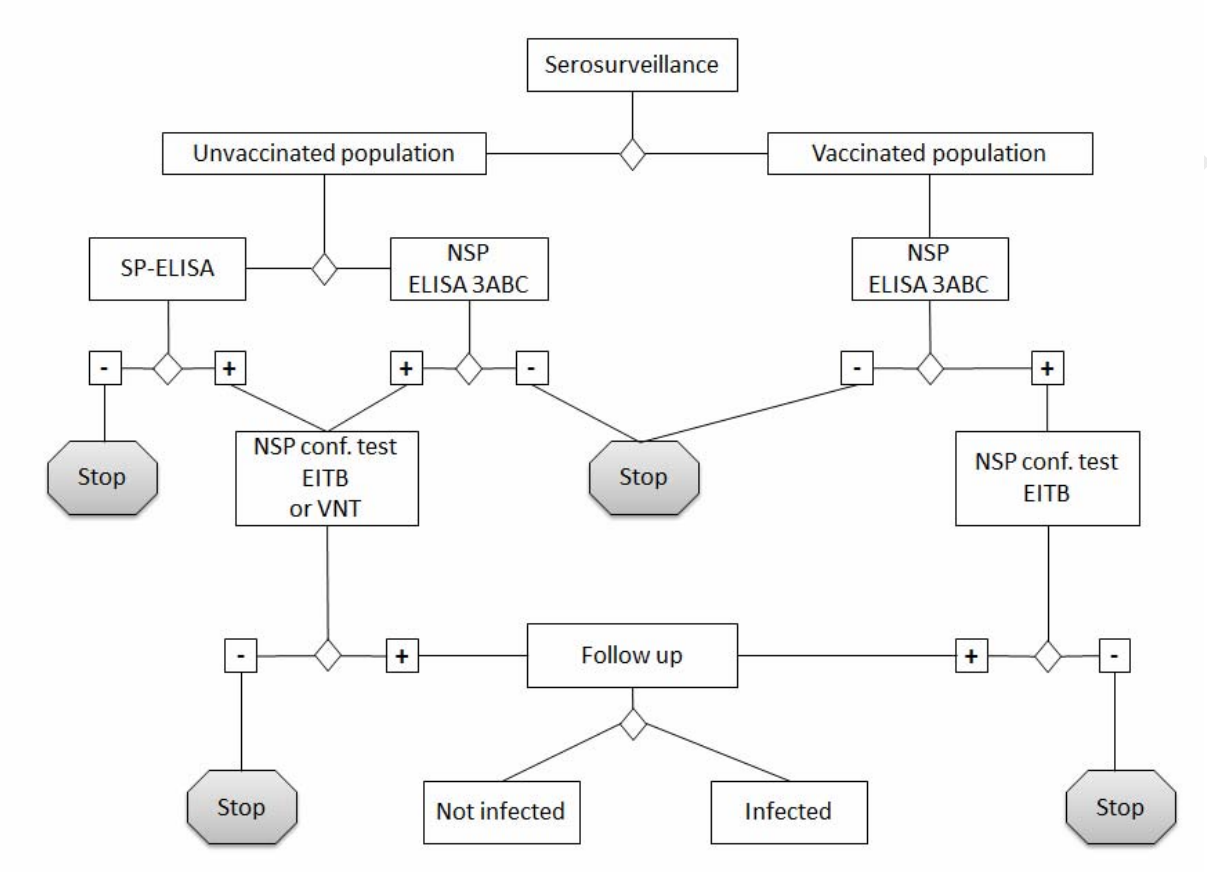
Annex XXXIX (contd)

Figure ~~1~~2: Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys



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Annex XL

CHAPTER 8.X.

INFECTION WITH *BRUCELLA ABORTUS, MELITENSIS* AND *SUIS*

Article 8.X.1.

General provisions

The aim of this chapter is to mitigate the risk of spread of, and the risk to human health from, *B. abortus, B. melitensis* and *B. suis* in *animals*.

For the purpose of this chapter:

– '*Brucella'* means *B. abortus, B. melitensis* or *B. suis,* excluding vaccine strains.

– ~~For the purpose of this chapter,~~ 'Animals' means domestic and *captive wild* animal populations of the following categories:

1) ~~Bovidae~~ bovids ; this term means cattle (*Bos taurus*, *B. indicus, B. frontalis*, ~~and~~ *B. javanicus*~~), yak (~~ and *B. grunniens*), bison (*Bison bison* and *B. bonasus*) and water buffalo (*Bubalus bubalis*);

2) ~~Ovidae and Capridae mean~~ sheep (*Ovis aries*) and goats (*Capra aegagrus*);

3) pigs ~~means domestic pigs and *wild* boars~~ (*Sus scrofa*);

4) ~~*Camelidae*~~ camelids; this term means dromedary camel (*Camelus dromedarius*), Bactrian camel (*Camelus bactrianus*), llama (*Lama glama*), alpaca (*Lama pacos*), guanaco *(Lama guanicoe*) and vicuna (*Vicugna vicugna*);

5) ~~*Cervidae*~~ cervids means roe deer (*Capreolus capreolus),* red deer *(Cervus elaphus elaphus),* wapiti/elk *(C. elaphus canadensis),* sika*(C. nippon)*, samba*(C. unicolor unicolor)*, rusa *(C. timorensis),* fallow deer *(Dama ~~dama~~ dama,*), white-tailed, black-tailed, mule deer (*Odocoileus* spp.) and reindeer (~~*Cervus elaphus elaphus, C. elaphus canadensis, C. nippon, C. unicolor unicolor, C. timorensis, Dama dama dama, Odocoileus virginianus borealis, O.docoileus hemionus columbianus, O.docoileus hemionus hemionus*~~ and *Rangifer tarandus*);

6) European hare (*Lepus europaeus*).

For the purpose of the *Terrestrial Code*, a *case* is an *animal* infected with *Brucella*.

The chapter deals not only with the occurrence of clinical signs caused by *Brucella infection*, but also with the presence of *Brucella infection* in the absence of clinical signs.

~~A *case* is an animal infected with *Brucella*.~~

The following defines ~~a *case* of~~ *Brucella infection*:

– *Brucella* has been ~~isolated and/or~~ identified ~~as such~~ from an *animal* or a product derived from that *animal*;

OR

– positive results to ~~one or more~~ a diagnostic test~~s~~ have been obtained and there is an epidemiological link to a confirmed *case* ~~evidence of *Brucella infection*~~.

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Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*. ~~In the absence of sufficient scientific information, the prescribed tests for bovines, except bovine specific indirect ELISAs, may be applied to *Cervidae* and *Camelidae*.~~

When authorising import or transit of *commodities* listed in this chapter, with the exception of those listed in Article 8.x.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Brucella infection* status of the animal population of the *exporting country*, *zone*, *herd* or *flock*.

Article 8.X.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Brucella*-related conditions, regardless of the *Brucella* *infection* status of the animal population of the *exporting country*, *zone*, *herd* or *flock*:

1) skeletal muscle *meat*, brain and spinal cord, digestive tract, thymus, thyroid and parathyroid glands and derived products~~, provided that they are accompanied by an *international veterinary certificate* attesting that they are originating from animals that have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.~~;

2) cured hides and skins;

3) gelatine, collagen, tallow and *meat-and-bone meal.*

~~When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Brucella* status of the animal population of the *exporting country*, *zone* or *herd* or *flock*.~~

Article 8.X.3.

Country or zone free from *Brucella* infection ~~in animals~~ without vaccination in bovids

~~A country or *zone* can be qualified free from *Brucella infection* without *vaccination* either in one or several of the animal categories listed in Article 11.3.1.~~

1) To qualify as free from *Brucella infection* without *vaccination* in bovids, a country or *zone* should satisfy ~~for each relevant category of animals~~ the following requirements:

   ~~1.~~a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

   ~~2.~~b) regulatory measures for the early detection ~~a programme should be in place to ensure effective reporting of all *cases* suggestive~~ of *Brucella infection* in bovids, ~~particularly abortions, and~~ including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

   ~~3.~~c) ~~neither domestic nor *captive wild* animals~~ no bovids have been vaccinated against *Brucella infection* for at least the past three years, and bovids that are introduced in the country or *zone* have not been vaccinated during the past three years;

   ~~4.~~d) no *case* of ~~abortion due to~~ *Brucella infection* ~~and no isolation of *Brucella*~~ has been recorded in ~~animals~~ bovids for at least the past three years;

~~5) except for pigs:~~

   e) bovids and their genetic materials introduced in the country or *zone* ~~should~~ comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

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~~a~~f) regular and periodic testing of all *herds* ~~or *flocks*~~ has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* ~~or *flocks* and~~ representing at least 99.9% of ~~animals~~ bovids in the country or *zone* ~~three consecutive years;~~.

2) To maintain the status as free from *Brucella infection* without *vaccination* in bovids, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a) to 1e) above are met;

b) a *surveillance* programme based on regular and periodic testing of ~~animals should be~~ bovids is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if ~~a~~ the *surveillance* programme described ~~in Points 2 and 5 a) and~~ b) above has not detected *Brucella infection* for ~~the past five~~ two consecutive years, *surveillance* ~~should~~ may be maintained in accordance with Chapter 1.4.

~~6.~~3) ~~vaccinated animals should not be introduced. Unvaccinated animals and genetic materials should comply with the recommendations in Articles 11.3.8. to 11.3.12.~~ The free status without *vaccination* of the country or *zone* ~~for~~ in bovids ~~a specified animal category~~ is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* ~~and~~ or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to ~~the relevant animal population~~ bovids ~~belonging to the specified animal category free from *Brucella infection* is effectively separated from the potential source of *infection*~~.

Article 8.X.4.

Country or zone free from *Brucella* infection ~~in animals~~ with vaccination in bovids

~~A country or *zone* can be qualified free from *Brucella infection* with *vaccination* either in bovines or ovidae and capridae as listed in Article 11.3.1.~~

1) To qualify as free from *Brucella infection* with *vaccination* in bovids, a country or *zone* should satisfy ~~for each relevant category of animals~~ the following requirements:

~~1.~~a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

~~2.~~b) regulatory measures for the early detection ~~a programme should be in place to ensure effective reporting of *all cases* suggestive~~ of *Brucella infection* in bovids, ~~particularly abortions, and~~ including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

~~3.~~c) vaccinated ~~animals~~ bovids should be identified with a permanent mark;

~~4.~~d) no *case* of ~~abortion due to~~ *Brucella infection* ~~and no isolation of *Brucella*~~ has been recorded in ~~animals~~ bovids for at least the past three years;

~~5~~e) bovids and their genetic materials introduced in the country or *zone* comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

f) regular and periodic testing of all *herds* ~~or *flocks*~~ has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* ~~or *flocks* and~~ representing at least 99.9% of ~~animals~~ bovids in the country or *zone*. ~~three consecutive years;~~

2) To maintain the status as free from *Brucella infection* with *vaccination* in bovids, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a) to 1e) above are met;

~~6.~~b) a *surveillance* programme based on regular and periodic testing of ~~animals should be~~ bovids is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

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c) if ~~a~~ the *surveillance* programme described in ~~Points 2 and 5 a) and~~ b) above has not detected *Brucella infection* for ~~the past five~~ two consecutive years, *surveillance* ~~should~~ may be maintained in accordance with Chapter 1.4.

~~7. 8. animals and genetic materials introduced should comply with the recommendations in Articles 11.3.8. to 11.3.12~~.

3) The free status with *vaccination* of the country or *zone* for bovids ~~a specified animal category~~ is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* ~~and~~ or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to ~~the relevant animal population~~ bovids ~~belonging to the specified animal category free from *Brucella infection* is effectively separated from the potential source of *infection*~~.

4) In addition, if a country or *zone* free from *Brucella infection* with *vaccination* in bovids wishes to change its status to country or *zone* free from *Brucella infection* without *vaccination*, the status of this country or *zone* remains unchanged for a period of at least three years after *vaccination* has ceased, provided that the requirements in point 1c) of Article 8.X.3. are met during that period.

Article 8.X.5.

Country or zone free from *Brucella* infection without vaccination in sheep and goats

1) To qualify as free from *Brucella infection* without *vaccination* in sheep and goats, a country or *zone* should satisfy the following requirements:

a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

b) regulatory measures for the early detection of *Brucella infection* in sheep and goats, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

c) no sheep and goats have been vaccinated against *Brucella infection* for at least the past three years and sheep and goats that are introduced in the country or *zone*, have not been vaccinated during the past three years;

d) no *case* of *Brucella infection* has been recorded in sheep and goats for at least the past three years;

e) sheep and goats and their genetic materials introduced in the country or *zone* comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

f) regular and periodic testing of all *flocks* has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *flocks* representing at least 99.9% of sheep and goats in the country or *zone*.

2) To maintain the status as free from *Brucella infection* without *vaccination* in sheep and goats, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a) to 1e) above are met;

b) a *surveillance* programme based on regular and periodic testing of sheep and goats is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if the *surveillance* programme described in b) above has not detected *Brucella infection* for two consecutive years, *surveillance* may be maintained in accordance with Chapter 1.4.

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3) The free status without *vaccination* of the country or *zone* in sheep and goats is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to sheep and goats.

Article 8.X.6.

Country or zone free from *Brucella* infection with vaccination in sheep and goats

1) To qualify as free from *Brucella infection* with *vaccination* in sheep and goats, a country or *zone* should satisfy the following requirements:

   a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

   b) regulatory measures for the early detection of *Brucella infection* in sheep and goats, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

   c) vaccinated sheep and goats should be identified with a permanent mark;

   d) no *case* of *Brucella infection* has been recorded in sheep and goats for at least the past three years;

   e) sheep and goats and their genetic materials introduced in the country or *zone* comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

   f) regular and periodic testing of all *flocks* have been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the f*locks* representing at least 99.9% of sheep and goats in the country or *zone*.

2) To maintain the status as free from *Brucella infection* with *vaccination* in sheep and goats, a country or *zone* should satisfy the following requirements:

   a) the requirements in points 1a) to 1e) above are met;

   b) a *surveillance* programme based on regular and periodic testing of sheep and goats is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

   c) if the *surveillance* programme described in b) above has not detected *Brucella infection* for two consecutive years, *surveillance* may be maintained in accordance with Chapter 1.4.

3) The free status with *vaccination* of the country or *zone* in sheep and goats is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to sheep and goats.

4) In addition, if a country or *zone* free from *Brucella infection* with *vaccination* in sheep and goats wishes to change its status to country or *zone* free from *Brucella infection* without *vaccination*, the status of this country or *zone* remains unchanged for a period of at least three years after *vaccination* has ceased, provided that the requirements in point 1c) of Article 8.X.5. are met during that period.

Article 8.X.7.

Country or zone free from *Brucella* infection in camelids

1) To qualify as free from *Brucella infection* in camelids, a country or *zone* should satisfy the following requirements:

   a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

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Annex XL (contd)

b) regulatory measures for the early detection of *Brucella infection* in camelids, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

c) no camelids have been vaccinated against *Brucella infection*;

d) no *case* of *Brucella infection* has been recorded in camelids for at least the past three years;

e) camelids and their genetic materials introduced in the country or *zone* comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

f) regular and periodic testing of all *herds* has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* representing at least 99.9% of camelids in the country or *zone*.

2) To maintain the status as free from *Brucella infection* in camelids, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1a) to 1e) above are met;

b) a *surveillance* programme based on regular and periodic testing of camelids is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if the *surveillance* programme described in b) above has not detected *Brucella infection* for two consecutive years, *surveillance* may be maintained in accordance with Chapter 1.4.

3) The free status of the country or *zone* in camelids is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to camelids.

Article 8.X.8.

Country or zone free from *Brucella* infection in cervids

1) To qualify as free from *Brucella infection* in cervids, a country or *zone* should satisfy the following requirements:

a) *Brucella infection* in *animals* is a *notifiable disease* in the country or *zone*;

b) regulatory measures for the early detection of *Brucella infection* in cervids, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

c) no cervids have been vaccinated against *Brucella infection*;

d) no *case* of *Brucella infection* has been recorded in cervids for at least the past three years;

e) cervids and their genetic materials introduced in the country or *zone* comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

f) regular and periodic testing of all *herds* has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* representing at least 99.9% of cervids in the country or *zone*;

2) To maintain the status as free from *Brucella infection* in cervids, a country or *zone* should satisfy the following requirements:

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a) the requirements in Points 1.a) to 1.e) above are met;

b) a *surveillance* programme based on regular and periodic testing of cervids is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if the *surveillance* programme described in b) above has not detected *Brucella infection* for two consecutive years, *surveillance* may be maintained in accordance with Chapter 1.4.;

3) The free status of the country or *zone* in cervids is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *Brucella infection* to cervids.

Article 8.X.9.

Herd or flock free from *Brucella* infection without vaccination in bovids, sheep and goats, camelids or cervids

1) To qualify as free from *Brucella infection* without *vaccination*, a *herd* or *flock* of ~~the relevant animal category~~ bovids, sheep and goats, camelids or cervids should satisfy the following requirements:

a) the *herd* or *flock* is in a country or *zone* free from *Brucella infection* without *vaccination* for the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*;

OR

b) the *herd* or *flock* is in a country or *zone* free from *Brucella infection* with *vaccination* for the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*; and no *animal* of the *herd* or *flock* has been vaccinated in the past three years;

OR

c) the *herd* or *flock* met the following conditions:

i) *Brucella infection* in *animals* is a *notifiable disease* in the country;

ii) no *animal* of the relevant category of the *herd* or *flock* has been vaccinated during the past three years;

iii) no *case* of *Brucella infection* has been detected in the *herd* or *flock* ~~has not shown evidence of *Brucella infection*~~ for at least the ~~past nine~~ past 12 months;

iv) *animals* showing clinical signs consistent with *Brucella infection* ~~all suspect cases~~ (such as ~~animals which have aborted~~ abortions) have been subjected to the necessary ~~clinical and laboratory investigations~~ diagnostic tests ~~with negative results~~;

v) for at least the past 12 months, there has been no evidence of *Brucella infection* in other susceptible *animals* of the same *epidemiological unit*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other susceptible *animals*;

~~v~~vi) all sexually mature *animals* of the relevant category, except castrated males were subjected to a prescribed ~~serological~~ test for *Brucella infection* with negative results on two occasions, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 months after the *slaughter* of the last *case*.

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Annex XL (contd)

2) To maintain the free status, the following conditions should be met:

a) the requirements in points 1a) or 1b) or 1c) i) to v) above are met;

~~a~~b) regular prescribed tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *Brucella infection*;

~~b~~c) *animals* of the relevant category introduced into the *herd* or *flock* are ~~should be~~ accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

i) a country or *zone* free from *Brucella infection* without *vaccination*;

OR

ii) a country or *zone* free from *Brucella infection* with *vaccination* and the *animals* of the relevant category have not been vaccinated during the past three years;

OR

iii) a *herd* or *flock* free from *Brucella infection* with or without *vaccination*~~,~~ and ~~provided~~ that the *animals* have not been vaccinated in the past 3 years and were subjected ~~negative results were shown~~ to a prescribed test for *Brucella infection* ~~during~~ within ~~the~~ 30 days prior to shipment with negative results; in the ~~*case*~~ case of post-parturient females ~~which have given birth during the past 30 days~~, the test is ~~should be~~ carried out at least 30 days after giving ~~the~~ birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.

~~c) There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.~~

Article 8.X.10.

Herd or flock free from *Brucella* infection with vaccination in bovids, sheep and goats

~~A *herd* or *flock* can be qualified free from *Brucella infection* with *vaccination* either in bovines or ovidae and capridae as listed in Article 11.3.1.~~

1) To qualify as free from *Brucella infection* with *vaccination*, a *herd* of bovids or *flock* of sheep and goats ~~the relevant animal category~~ should satisfy the following requirements:

a) the *herd* or *flock* is in a country or *zone* free from *Brucella infection* with *vaccination* for the relevant animal category and is certified free with *vaccination* by the *Veterinary Authority*;

OR

b) the *herd* or *flock* met the following conditions:

i) *Brucella infection* in *animals* is a *notifiable disease* in the country;

ii) vaccinated *animals* of the relevant categories ~~should be~~ are permanently identified;

iii) no *case* of *Brucella infection* has been detected in the *herd* or *flock* ~~has not shown evidence of *Brucella infection*~~ for at least the past ~~nine~~ 12 months;

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iv) *animals* of the relevant category showing clinical signs consistent with *Brucella infection* ~~all suspect cases~~ (such as ~~animals which have aborted~~ abortions) have been subjected to the necessary ~~clinical and laboratory investigations~~ diagnostic tests ~~with negative results~~;

v) for at least the past 12 months, there has been no evidence of *Brucella infection* in other susceptible *animals* of the same *epidemiological unit*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other susceptible *animals*;

~~v~~vi) all sexually mature *animals* of the relevant category except castrated males were subjected to a prescribed ~~serological~~ test for *Brucella infection* with negative results on two occasions, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 months after the *slaughter* of the last *case*.

2) To maintain the free status, the following conditions should be met:

a) the requirements in points 1 a) or 1b) i) to v) above are met;

~~a~~b) regular prescribed tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *Brucella infection*;

~~b~~c) *animals* of the relevant category introduced into the *herd* or *flock* should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from either:

i) a country or *zone* free from *Brucella infection* with or without *vaccination*;

OR

ii) a *herd* or *flock* free from *Brucella infection* with or without *vaccination*~~,~~ and ~~provided~~ that the *animals* have not been vaccinated in the past 3 years and were subjected ~~negative results were shown~~ to a prescribed test for *Brucella infection* within ~~during the~~ 30 days prior to shipment with negative results; in the ~~*case*~~ case of post-parturient females ~~which have given birth during the past 30 days~~, the test is ~~should be~~ carried out at least 30 days after giving ~~the~~ birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.

~~c) There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.~~

Article 8.X.11.

Herd free from *Brucella* infection in pigs

1) To qualify as free from *Brucella infection*, a *herd* of pigs should satisfy the following requirements:

a) *Brucella infection* in *animals* is a *notifiable disease* in the country;

b) no pigs of the *herd* have been vaccinated;

c) no *case* of *Brucella infection* has been detected in the *herd* for at least the past three years;

d) *animals* showing clinical signs consistent with *Brucella infection* (such as abortions or orchitis) have been subjected to the necessary diagnostic tests;

e) for at least the past three years, there has been no evidence of *Brucella infection* in other susceptible *animals* of the same *epidemiological unit*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other susceptible *animals*.

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Annex XL (contd)

2) To maintain the free status, the following conditions should be met:

a) the requirements in point 1) above are met;

b) *animals* introduced into the *herd* are accompanied by a certificate from an *Official Veterinarian* attesting that:

i) they come from a *herd* free from *Brucella infection*;

OR

ii) they come from a *herd* in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Chapter 1.4., was subjected to a prescribed test within 30 days prior to shipment, demonstrating the absence of *Brucella infection;*

OR

iii) they were subjected to a prescribed test within 30 days prior to shipment with negative results.

Article 8.X.12.

Recovery of the *Brucella* infection free status in a country or a zone

Should a *case* of *Brucella infection* in one or more animal categories occur in a free country or *zone* as described in Articles 8.X.3. to 8.X.8., ~~the status is suspended~~ the free status ~~and~~ may ~~not~~ be recovered ~~until~~ once the following requirements are met:

1) all infected *animals* of the relevant category ~~were~~ are slaughtered or destroyed as soon as *Brucella infection* is confirmed ~~the result of the diagnostic test was known~~;

2) an epidemiological investigation is performed within 60 days of *Brucella infection* confirmation in the *herd* or *flock*, aiming at identifying the likely source and the distribution of the *infection,* and shows that *Brucella infection* has spread to less than 0.2% of *herds* or *flocks*;

3) in the *herds* or *flocks* identified by the epidemiological investigation:

a) depopulation is practised; or,

~~2.~~b) depopulation is not practised ~~in animal categories other than pigs~~, and all remaining sexually mature *animals* ~~in the *herd* or *flocks*~~ except castrated males have been subjected to a ~~serological~~ prescribed test, with negative results, on three occasions, at an interval of not less than two months, then a ~~further~~ fourth test six months later and a final fifth test a year later;

c) no *animals* are moved from the *herds* or *flocks* except for direct *slaughter* until the processes in point a) or b) above are completed;

~~3.~~4) ~~in pig *herds*, where *cases* of *Brucella infection* have occurred, all pigs were slaughtered or destroyed~~ cleansing and *disinfection* procedures have been applied at the end of the *slaughter* process and before new *animals* are introduced.

When these requirements are not met, Articles 8.X.3. to 8.X.8. apply as relevant.

Article 8.X.13.

Recommendations for the importation of ~~animals~~ bovids, sheep and goats, camelids or cervids for breeding or rearing

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary*

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certificate attesting that the *animals* of the relevant category:

Annex XL (contd)

1) showed no clinical signs of *Brucella infection* on the day of shipment;

2) originate from:

   a) a country or *zone* free from *Brucella infection* as relevant;

   OR

   b) a *herd* or *flock* free from *Brucella infection* and all sexually mature *animals* were subjected to a prescribed ~~serological~~ test for *Brucella infection* with negative results ~~during~~ within ~~the~~ 30 days prior to shipment.

      ~~This test is not required for:~~

      – ~~pigs;~~

      – ~~young bovines before the age of 12 months;~~

      – ~~young ovidae and capridae before the age of 6 months;~~

      – ~~young *Camelidae* and *Cervidae* before the age of sexual maturity;~~

   OR

   c) ~~with the exception of pigs,~~ a *herd* or *flock* not qualified free from *Brucella infection*:

      i) in which no *Brucella infection* has been reported during the nine 12 months prior to shipment;

      ii) the *animals* were isolated for 30 days prior to shipment and subjected ~~during~~ within that period to a prescribed ~~serological~~ test for *Brucella infection* with negative results; in the ~~case~~ case of post-parturient females ~~which have given birth during the past 30 days~~, the test is ~~should be~~ carried out at least 30 days after giving ~~the~~ birth. ~~This test is not required for sexually immature animals or vaccinated animals less than 18 months of age~~.

Article 8.X.14.

Recommendations for the importation of pigs for breeding or rearing

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the pigs:

1) showed no clinical signs of *Brucella infection* on the day of shipment;

2) either:

   a) originate from a *herd* free from *Brucella infection*;

   OR

   b) originate from a *herd* in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Chapter 1.4., was subjected to a prescribed test within 30 days prior to shipment, demonstrating the absence of *Brucella infection*;

   OR

   c) were subjected to a prescribed test for *Brucella infection* within 30 days prior to shipment with negative results.

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Annex XL (contd)

Article 8.X.15.

Recommendations for the importation of animals for slaughter

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical signs of *Brucella infection* on the day of shipment;

2) originate from a country, *zone, herd* or *flock* free from *Brucella infection* ~~with or without *vaccination*~~;

   OR

3) are not being eliminated as part of an eradication programme against *Brucella infection* and in the case of sexually mature bovids, sheep and goats, camelids or cervids, were subjected to a prescribed test for *Brucella infection* with negative results ~~during~~ within ~~the~~ 30 days prior to shipment ~~and are not being eliminated as part of an eradication programme against *Brucella infection*~~.

~~Article 11.3.10.~~

~~**Recommendations for the importation of captive European hares (*Lepus europaeus*) for restocking**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:~~

~~1) the animals showed no clinical signs of *Brucella infection* on the day of shipment;~~

~~2) a programme is in place to ensure effective investigation and reporting of all *cases* suggestive of *Brucella infection* in *establishments* keeping hares.~~

Article 8.X.16.

Recommendations for the importation of semen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals* showed no clinical signs of *Brucella infection* on the day of collection of the semen;

2) the donor *animals* were not vaccinated against *Brucella infection* and either:

   a) were kept in an *artificial insemination centre* ~~free from *Brucella infection*~~;

      OR

   b) were kept in a *herd* or *flock* free from *Brucella infection* and ~~are~~ subjected every six months to a prescribed test for *Brucella infection* with negative results, and the semen was collected, processed and stored in conformity with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.

~~3) the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.~~

Article 8.X.17.

Recommendations for the importation of embryos and oocytes

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary*

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certificate attesting that:

Annex XL (contd)

1) the donor *animals* showed no clinical signs of *Brucella infection* on the day of collection;

2) the donor *animals* were not vaccinated against *Brucella infection* during the past three years and either:

   a) were kept in a country or *zone* free from *Brucella infection,* as relevant;

      OR

   b) were kept in a *herd* or *flock* free from *Brucella infection* and ~~are~~ subjected every six months to a prescribed test for *Brucella infection* with negative results;

3) the embryos and oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7. to Chapter 4.9.

Article 8.X.18.

Recommendations for the importation of fresh meat and meat products other than mentioned in Article 8.X.2.

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *meat* and *meat products* come from *animals*:

1) which have been subjected to ante-~~mortem~~ and post-mortem inspections as described in Chapter 6.2.;

2) which:

   a) originate from a country or *zone* free from *Brucella infection,* as relevant;

   OR

   ~~a~~b) originate from a *herd* or *flock* free from *Brucella infection*;

   OR

   ~~b~~c) have not been eliminated as part of an eradication programme against *Brucella infection* ~~have not tested positive to a prescribed test for *Brucella infection*~~.

Article 8.X.19.

Recommendations for the importation of milk and milk products

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *milk* or the *milk products*:

1) have been derived from *animals* in a country*, zone, herd* or *flock* free ~~of a *herd* or *flock* free~~ from *Brucella infection*;

   OR

2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

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Annex XL (contd)

Article 8.X.20.

Recommendations for importation of wool and hair

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products:

1) have not been derived from ~~*Brucella* infected~~ *animals* eliminated as part of an eradication programme against *Brucella infection*;

OR

2) have been processed to ensure the destruction of the *Brucella*.

Article 8.X.21.

Procedures for the inactivation of *Brucella* in casings of bovids, sheep and goats, and pigs

For the inactivation of *Brucella* in casings of bovids, sheep and goats, and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (Aw < 0.80), and kept at a temperature of greater than 20°C during this entire period.

— Text deleted.

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Annex XLI

CHAPTER X.X.

INFECTION WITH EPIZOOTIC HEMORRHAGIC DISEASE VIRUS

Article X.X.1.

General provisions

For the purposes of the *Terrestrial Code*, epizootic hemorrhagic disease (EHD) is defined as an *infection* of cervids and bovids ~~cattle~~ with one of several serotypes of epizootic hemorrhagic disease virus (EHDV). *Outbreaks* of *disease* due to EHDV are sporadic and geographically restricted. Although EHDV is not regarded as a significant pathogen of livestock in many countries in which it is present, *outbreaks* of *disease* have caused significant economic loss to the cattle industry in some countries.

The following defines the occurrence of EHDV *infection*:

1) EHDV has been isolated and identified as such from a cervid or bovid or a product derived from it; or

2) viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of EHDV has been identified in samples from a cervid or bovid showing clinical signs consistent with EHD, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with EHDV; or

3) antibodies to structural or nonstructural proteins of EHDV that are not a consequence of *vaccination* have been identified in a cervid or bovid that either shows clinical signs consistent with EHD, or is epidemiologically linked to a confirmed or suspected *case*, or gives cause for suspicion of previous association or contact with EHDV.

For the purposes of *international trade*, a distinction is made between a *case* as defined above and an *animal* that is potentially infectious to *vectors*.

For the purposes of the *Terrestrial Code*, the *infective period* for EHDV shall be 60 days.

For countries that do not meet the provisions of point 1 of Article 1.4.6. and in the absence of clinical *disease* in a country or *zone*, its EHDV status should be determined by an ongoing *surveillance* programme (in accordance with Article x.x.~~16~~12.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology.

Standards for diagnostic tests ~~and vaccines~~ are described in the *Terrestrial Manual*.

Article X.X.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any EHDV related conditions regardless of the EHDV status of the ruminant population of the *exporting country* or *zone*:

1) *milk* and *milk products*;

2) *meat* and *meat products*;

3) hides, skins, antlers and hooves;

4) wool and fibre.

Annex XLI (contd)

Article X.X.3.

EHDV free country or zone

1) A country or a *zone* may be considered free from EHDV when EHD ~~epizootic haemorrhagic disease~~ is notifiable in the whole country and either:

   a) historical freedom has been demonstrated as described in Article 1.4.6.; or

   b) a *surveillance* programme in accordance with Article X.X.~~16~~12. has demonstrated no evidence of EHDV transmission in the country or *zone* during the past two years; or

   c~~b~~) an ongoing *surveillance* programme has demonstrated no evidence of *Culicoides* in the country or *zone*.

2) An EHDV free country or *zone* in which ongoing *vector surveillance* has found no evidence of *Culicoides* will not lose its free status through the importation of seropositive or infective *animals*, or semen, embryos or ova from infected countries or *infected zones*.

3) An EHDV free country or *zone* in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the importation of seropositive *animals,* provided that they were imported in accordance with Article X.X.6.

~~Article X.X.4.~~

~~**EHDV seasonally free zone**~~

~~An EHDV seasonally free *zone* is a part of an infected country or an *infected zone* for which for part of a year *surveillance* demonstrates no evidence either of EHDV transmission or of adult *Culicoides*.~~

Article X.X.~~5~~4.

EHDV infected country or zone

For the purpose of this chapter, an EHDV infected country or *infected zone* is a clearly defined area where evidence of EHDV transmission has been reported during the past two years. ~~Such a country or *zone* may contain an EHDV seasonally free *zone*.~~

Article X.X.~~6~~5.

Recommendations for importation from EHDV free countries or zones

For cattle and cervids

Where EHDV is of concern*, Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the *animals* were kept in an EHDV free country or *zone* since birth or for at least 60 days prior to shipment; or

2) the *animals* were kept in an EHDV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the EHDV group and remained in the EHDV free country or *zone* until shipment; or

3) the *animals* were kept in an EHDV free country or *zone* for at least seven days, then were subjected, with negative results, to an agent identification test and remained in the EHDV free country or *zone* until shipment;

AND

4) if the *animals* were exported from a free *zone* within an *infected country* either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attacks by *Culicoides* at all times when transiting through an *infected zone.*

~~Article X.X.7.~~

~~**Recommendations for importation from EHDV seasonally free zones**~~

~~For cattle and cervids~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals*:~~

~~1) were kept during the seasonally free period in an EHDV seasonally free *zone* since birth or for at least 60 days prior to shipment; or~~

~~2) were kept during the EHDV seasonally free period in an EHDV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the EHDV group with negative results, carried out at least 28 days after the commencement of the residence period; or~~

~~3) were kept during the EHDV seasonally free period in an EHDV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test with negative results, carried out at least 14 days after the commencement of the residence period;~~

~~AND~~

~~4) either:~~

   ~~a) did not transit through an *infected zone* during transportation to the *place of shipment*; or~~

   ~~b) were protected from attacks by *Culicoides* at all times when transiting through an *infected zone.*~~

Article X.X.~~8~~6.

Recommendations for importation from EHDV infected countries or zones

For cattle and cervids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) were protected from attacks by *Culicoides* in a *vector*-protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

2) were protected from attacks by *Culicoides* in a *vector*-protected *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test to detect antibody to the EHDV group, with negative results, carried out at least 28 days after introduction into the *vector*-protected *establishment*; or

Annex XLI (contd)

3) were protected from attacks by *Culicoides* in an *vector*-protected *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test with negative results, carried out at least 14 days after introduction into the *vector*-protected *establishment*; or

4) were demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Article x.x.~~16~~12.

Article X.X.~~9~~7.

Recommendations for importation from EHDV free countries or zones

For semen of cattle and cervids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) were kept in an EHDV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after the last collection for this consignment, with negative results; or

   c) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

~~Article X.X.10.~~

~~**Recommendations for importation from EHDV seasonally free zones**~~

~~For semen of cattle and cervids~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

~~1) the donor *animals*:~~

~~a) were kept during the EHDV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or~~

~~b) were subjected to a serological test to detect antibody to the EHDV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or~~

~~c) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;~~

~~2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.~~

Article X.X.~~11~~8.

Recommendations for importation from EHDV infected countries or zones

For semen of cattle and cervids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test to detect antibody to the EHDV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article X.X.~~12~~9.

Recommendations for importation from EHDV free countries or zones

For embryos or oocytes of cattle and cervids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) were kept in an EHDV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos or oocytes; or

   b) were subjected to a serological test ~~t~~o detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

2) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

~~Article X.X.13.~~

~~**Recommendations for importation from EHDV seasonally free zones**~~

~~For embryos or oocytes of cattle and cervids~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

~~1) the donor females:~~

   ~~a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos or oocytes; or~~

   ~~b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or~~

Annex XLI (contd)

~~c) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;~~

~~2) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.~~

Article X.X.~~14~~10.

Recommendations for importation from EHDV infected countries or zones

For embryos or oocytes of cattle and cervids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the embryos or oocytes; or

   b) were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

2) the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article X.X.~~15~~11.

Protecting animals from Culicoides attacks

1. Vector-protected establishment or facility

   Where movement of *animals* or collection of genetic material requires a vector-protected facility, the *establishment* or facility should be approved by the *Veterinary Authority* and the following criteria apply:

   a) appropriate physical barriers at entry and exit points, for example, double-door entry-exit system;

   b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide according to the manufacturer's instructions;

   c) *vector* surveillance and control within and around the building;

   d) measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;

   e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of *animals* to the place of *loading*.

2. During transportation

When transporting *animals* through EHDV infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect *animals* from attacks by *Culicoides* during transport.

Risk management strategies may include:

a) *loading*, transporting and *unloading animals* at times of low *vector* activity (i.e. bright sunshine, low temperature);

b) ensuring *vehicles* do not stop en route during times of high *vector* activity (i.e. dawn or dusk, or overnight).

Article X.X.~~16~~12.

Surveillance

This article is complementary to Chapters 1.4. and 1.5. and outlines the principles for EHDV *surveillance* applicable to Members seeking to determine the EHDV status of a country or a *zone*.

The impact and epidemiology of EHD differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. It is incumbent upon Members to provide scientific data that explain the epidemiology of EHD in the region concerned and adapt the *surveillance* strategies for defining their infection status (free ~~, seasonally free~~ or infected country or *zone*) to the local conditions. There is considerable latitude available to Members to justify their infection status at an acceptable level of confidence.

Surveillance for EHD should be in the form of a continuing programme.

General provisions on surveillance for arthropod *vectors* are in Chapter 1.5.

More specific approaches to *surveillance* for *Culicoides* transmitted *Orbivirus infections* are described in Chapters 8.3. and 12.1. Passive *surveillance* for clinical *cases* of EHD in susceptible wild ruminants can be a useful tool for detecting *disease*, based on lesions of haemorrhagic disease combined with viral detection techniques.

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Annex XLII

CHAPTER 4.X.

GENERAL PRINCIPLES FOR ANIMAL DISEASE CONTROL

Article 4.X.1.

Introduction and objectives

This chapter is intended to help Member Countries identify priorities, objectives and the desired goal of *disease* control programmes in endemic, *outbreak* or emergency situations. *Disease* control programmes are often established with the aim of eventual eradication of agents at a country, *zone* or *compartment* level. While this approach is desirable, the needs of stakeholders may require a broader range of outcomes. For some *diseases*, eradication may not be economically or practically feasible and options for sustained mitigation of *disease* impacts may be needed. It is important to clearly describe the programme goals and these may range from simple mitigation of *disease* impacts to progressive control or eradication. The chapter highlights the importance of *disease* intervention options in the design of programmes, taking into consideration effectiveness, feasibility of implementation, and costs and benefits. The purpose is to provide a conceptual framework that can be adapted to a particular national and epidemiological context.

It is assumed that the country should have determined its *disease* control priorities and this chapter should help in the development and implementation of a specific programme that includes objectives, policies and strategies adapted to the full range of national needs. Specific outputs of this process will include the rationale for establishing a *disease* control programme, strategic goal and objectives, a control programme plan and implementation.

These general recommendations may be refined by the approaches described in the specific *disease* chapters. Where specific information on an *official control programme* is not available, suitable approaches should be based on the recommendations in this chapter.

Article 4.X.2.

Rationale for establishing a disease control programme

The country should clearly state the rationale for establishing a *disease* control programme. In addition to animal health, consideration should be given to public health, food safety, food security, biodiversity and socioeconomic aspects.

The justification for the *disease* control programme should include a summary of the current knowledge of the epidemiological situation in the country, providing for example detailed information on:

1) description of the *disease* situation;

2) description of *disease* impacts (animal and public health, food safety, food security and socioeconomic impact) and how these are distributed among stakeholders;

3) identification, level of interest and involvement of stakeholders.

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Article 4.X.3.

Control programme goal and objectives

The goal of a control programme should be defined. Although eradication has traditionally been the goal for many *disease* control programmes, it may not always be achievable within a reasonable time frame or at an acceptable cost. The epidemiology of the *disease,* along with the availability of technical tools as well as social, environmental and economic considerations, should dictate if eradication is achievable or if control at a certain prevalence level is the desired outcome. For some *diseases*, or in certain situations, the emphasis of a programme may be limited to reducing health and economic impacts. In other cases a programme may not be feasible or cost-beneficial. Specific objectives and indicators leading to achievement of the programme goal should be established.

Some of the factors to define the goal of *disease* control programmes are listed (Table 1). An assessment of these factors should guide in the strategic planning and programme implementation.

Table 1 – Factors to consider in setting achievable goals for disease control programmes

Biological factors - Species affected - Genetic stability and diversity of the agent - Density of susceptible species - Wildlife reservoir - Vector transmission - Transmissibility - Current extent of disease - Survival in the environment - Carrier state - Ease of clinical recognition	**Availability of technical tools** - Diagnostic tests - Vaccines - Treatment - Disinfectants and insecticides - Disposal facilities
Control measures - Movement control - Stamping-out, slaughter or pre-emptive slaughter - Import or export restrictions - Zoning or compartmentalisation - Herd accreditation - Isolation and quarantine - Cleaning and disinfection - Vector and reservoir control - Treatment of products and by-products - Vaccination	**Socioeconomic considerations** - Cost and benefits of intervention - Availability of resources - Structure of livestock production systems - Public health implications - Logistics and ease of implementation, - Stakeholder engagement - Environmental impact - Political will - Incentives and compensation - Acceptance of the public (e.g. animal welfare implications, culling of animals, destruction of food) - Safe commodities for trade - Institutional arrangements

Article 4.X.4.

Programme planning

The *Veterinary Authority,* in collaboration with stakeholders, should develop a plan based on the goal of the programme. Intervention options should be based on biological effectiveness, ease and cost of implementation, as well as the expected benefits. Tools such as value chain analysis may be used to help

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understand the role of different players within the production system, identify critical control points to target measures and provide an indication on the incentives for and feasibility of implementation of the programme.

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The decision on the most appropriate intervention options should take into account cost-benefit considerations, in conjunction with the likelihood of success of a particular set of *disease* control measures.

Institutional analysis examines the organisations involved in delivering services and the processes that govern their interaction. This type of analysis would be helpful to inform the strategic planning process and identify areas where a change would enable better programme implementation and facilitate effective collaboration.

The programme should include a continued review process to assess the effectiveness of the interventions being applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required.

The programme should take into consideration the distribution of costs and benefits among different stakeholders and understand the factors limiting stakeholder participation in programme activities. These factors can affect the optimal selection of interventions. Programme policies need to include incentives for engagement including additional services for the holder or producer, appropriate compensation schemes, adding value to the final product and protecting public health. In addition, it may be necessary to include measures to raise awareness and ensure compliance including movement restrictions and fines. *Disease* control programmes should take into consideration non-financial factors (social, cultural, religious, etc.) affecting the livelihoods and well-being of animal owners such as pastoralists, indigenous communities or small-scale backyard holders or producers. These factors can be important incentives for participation or non-compliance and ultimately impact the success of the programme.

Article 4.X.5.

Implementation plan

A *disease* control programme should be based on an efficient and effective *Veterinary Services* and holder or producer participation. Countries are encouraged to follow the provisions of Chapter 3.1., as well as to undergo a Performance of Veterinary Services (PVS) evaluation and address the gaps that may be identified. In addition, the programme should have political support, and sustainable sources of funding, including government and private stakeholder contributions.

The implementation plan should address the following:

1. Regulatory framework

   The *disease* control programme should be supported by effective legislation at the primary and secondary levels. Countries are encouraged to follow the OIE standards on Veterinary Legislation (Chapter 3.4.). The *disease* should be notifiable throughout the country. The regulatory framework for the *disease* control programme should be adapted to evolving programme needs.

2. Programme management

   Disease control measures to be applied in the programme may be implemented by the *Veterinary Authority*, or private or community entities or a combination of all. In any event, the overall responsibility for oversight of the programme remains with the *Veterinary Authority*.

   The management of the application of *disease* control measures should follow standard operating procedures including:

   a) implementation, maintenance, monitoring of the measures;

   b) application of corrective actions;

   c) verification of the process;

   d) record keeping including information systems and data management.

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3. Epidemiological situation

The implementation of the programme needs to take into consideration:

a) distribution and density of susceptible species including *wildlife*, if applicable;

b) knowledge of animal production and marketing systems;

c) spatial and temporal distribution of *disease;*

d) zoonotic potential;

e) risk factors and critical control points;

f) *vectors*;

g) carriers;

h) reservoirs;

i) impact of *disease* control measures;

j) specific *disease* situation in neighbouring country(ies), if applicable;

k) evaluation of appropriateness of establishing *disease zones* or *compartments.*

4. Disease surveillance

The underpinning of the *disease* control programme activities is an effective *surveillance* system that provides guidance on priorities and targets for the application of interventions. The *surveillance* system should consist of general *surveillance* activities reinforced by pathogen specific activities. A clear *case* definition and *outbreak* investigation and response procedures are required. The provisions of Chapters 1.1., 1.4. and 1.5. should be referred to and specific *surveillance* guidelines where applicable for particular *diseases*.

5. Diagnostic capability

The programme should be supported by diagnostic facilities with adequate capability and capacity. Samples for diagnosis should be collected and shipped in accordance with Chapter 1.1.1. of the *Terrestrial Manual.* The choice of diagnostic tests should ensure detection and confirmation of the *disease*. The tests should follow the specific requirements in Chapter 1.1.5. and the *disease* specific recommendations in the *Terrestrial Manual.* Diagnostic facilities, either official or accredited, should be under a quality assurance scheme coordinated by the designated national reference laboratory. The latter should establish communication with an OIE Reference Laboratory for the particular *disease*. National and sub-national laboratories need to ensure that diagnostic results are communicated to the *Veterinary Authority* as appropriate to the situation. National laboratories are also needed to provide independent and impartial quality control of vaccines. When appropriate, national laboratories are encouraged to submit samples to OIE Reference Laboratories for confirmation of findings and more detailed analysis.

6. Vaccination and other control measures

Vaccination is one of the essential tools in the control of many *diseases*, if an effective vaccine is available. However, *vaccination* on its own will not usually achieve the desired results unless the *vaccination* programme is part of an integrated control strategy utilising a combination of control measures as outlined in Table 1. If *vaccination* is applied the following points should be considered:

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a) Role of vaccination

Depending on the epidemiological situation, the pattern of animal movements, population density and production systems within the country, the occurrence of *wildlife* reservoirs, targeted *vaccination* may be more effective than systematic mass *vaccination*. *Vaccination* campaigns should be serologically monitored for their effectiveness to ensure that immunity objectives are being met. When a validated strategy to differentiate infected and vaccinated animals (DIVA) is available, its use should be considered.

b) Vaccine quality

A vaccine quality assurance programme ensures the purity, safety, potency of vaccines as well as measures their efficacy in relation to the circulating strains. Vaccines used within control programmes should be licensed under the authority of the official *Veterinary Services* in accordance to the provisions of the *Terrestrial Manual* and preferably tested by an independent authority for safety and potency.

c) Vaccine delivery

Effective delivery of vaccine, including preservation of the cold chain requirements and proper administration, is essential for reaching an adequate level of population immunity. This could require the implementation of governmental or private schemes that include quality assurance controls of vaccine distribution.

d) Vaccine and antigen banks

Vaccine and antigen banks may be useful to ensure that sufficient stocks are available. These may be held at national or regional level and should comply with the provisions of Chapter 1.1.10. of the *Terrestrial Manual.*

e) Other measures

Regardless of whether *vaccination* is used or not, a disease control programme should utilise a mix of control measures and tools. Several measures frequently applicable in a disease control programme are listed in Table 1.

7. Traceability

An effective traceability system facilitates the identification of affected individual *animals*, *herds* or *flocks*. The design of the traceability system should follow the provisions of Chapter 4.1. and Chapter 4.2.

8. Regional integration

Many diseases are considered transboundary animal diseases and require a regional control approach. Regional and inter-sectorial agreements, including the *Veterinary Authority* in each country and representatives from international and other relevant regional organisations, should be established to ensure proper coordination. Where possible, Member Countries should cooperate on a regional basis to harmonise disease control programmes.

9. Social participation

Communication, awareness programmes and programme ownership need to be in place. Stakeholders should be involved in the development, planning, implementation, management and revision of the programme. This should be an on-going process.

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10. Role of research in support of disease control programmes

During the strategic planning and assessment of programmes certain areas needing further research may be identified. Communication with national and international research institutions should be established to address programme needs.

11. Training and capacity building

Institutional capacity building is important in the development of systems and infrastructure. The personnel in charge of implementing the measures within the programme need to be adequately trained and updated on the current knowledge of the *disease*. Veterinary accreditation schemes of private *veterinarians* and *veterinary para-professionals* can be a useful tool to increase the veterinary presence in the field; however, training and supervision coordinated by the *Veterinary Authority* is required.

Article 4.X.6.

Outbreak investigation

An *outbreak* investigation is a systematic procedure to help identify the cause and source of *cases* with a view to control and prevent possible future occurrence. *Outbreak* investigation is an important responsibility of the *Veterinary Services* to ensure that preventive and control measures are applied. Investigations also help recognise intervention strategy failures and successes, identify changes in the agent, environment or events that may be beyond the scope of a disease control programme. It is important to maintain records of *outbreak* investigations including those which were not confirmed as this will help demonstrate the effectiveness of the *surveillance* system.

The main steps of outbreak investigation include:

1) preparation for field work;

2) establishment of the validity of the report triggering the investigation;

3) confirmation of diagnosis;

4) intensive follow-up and tracing;

5) collection and analysis of data including the characterisation of the event describing the *animals* involved and the spatial and temporal distribution;

6) implementation of control and preventive measures;

7) documentation and reporting.

A field investigation often entails doing several of these steps simultaneously. Two pathways are possible after the clinical investigation. If in the context of the disease control programme, clinical and epidemiological information may be sufficient to take action and no further laboratory investigation may be required. On the other hand, if the information is inconclusive, further laboratory and epidemiological investigation are needed. Control measures are usually implemented from the beginning of the investigation and modified as appropriate during the process. Laboratory characterisation of the agent may be important to the long term management of the programme.

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Article 4.X.7.

Emergency preparedness and contingency planning

1) Member Countries should develop emergency preparedness and contingency plans for immediate action for *listed* and *emerging diseases*. Emergency response plans should be up to date, tested in a simulation exercise and embedded in the legal framework. Emergency funds should be available to cover operational costs and indemnities. The chain of command and coordination with all key participants and relevant support services, when necessary, should be well established to ensure control efforts are executed rapidly and with success.

2) A contingency plan is a set of activities, including immediate actions and longer term measures, for responding to *disease outbreaks*. The process in developing a contingency plan is important to ensure successful implementation when an emergency occurs. It involves organising a team representing relevant authorities and stakeholders, identifying critical resources and functions, and establishing a plan for recovery. The plan should be simple and implementable. It should be documented, tested and updated regularly.

   The plan should be put together by the *veterinary authority*, involving representatives from local government, different relevant agencies and private sector representatives. Key components in a contingency plan include:

   a) established chain of command;

   b) systems for rapid detection and confirmation;

   c) *outbreak* investigation procedures;

   d) rapid containment measures (e.g. movement control, *disinfection*, *vaccination*, culling);

   e) communication strategy.

3) Notification of disease confirmation should be sent immediately to appropriate ministries, trading partners, stakeholders and should generally be made available to the general public. In addition, notification to the OIE should follow the provisions of Chapter 1.1.

4) Following the official confirmation of an *outbreak*, control areas may be established around the affected premises. The extent of these areas depends on a number of factors, in particular, the epidemiology of the *disease* in question. The measures imposed will often include movement restrictions, intensified *surveillance* as well as specific measures applied to affected premises. In addition, for ease of management and for trade purposes, a larger area surrounding the control areas may be designated corresponding to administrative boundaries, geographical or other appropriate features.

5) Disease control measures usually have a significant economic impact; therefore, appropriate compensation mechanisms are needed to ensure cooperation by farmers. Lack of compensation could result in non-compliance. Partnerships between government and the private sector have proven effective to develop sustainable contingency funds in several parts of the world.

6) It is important that this plan be coordinated on a regional level, particularly for transboundary animal diseases.

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Annex XLII (contd)

Where possible, Member Countries should act on a regional basis to ensure that funds and resources are available in an emergency and to protect the region from disease incursion and spread.

Detailed guidance and examples of contingency plans are available on the OIE web site: (http://www.oie.int/en/animal-health-in-the-world/the-world-animal-health-information-system/national-disease-contingency-plans).

Article 4.X.8.

Monitoring, evaluation and review

The programme should include a continued review process to assess the effectiveness of the interventions applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required. This process should begin with the establishment of baseline data on the epidemiological, economic and social impact of the *disease*. The programme should collect data on process and impact indicators. This enables measurement of the effectiveness of interventions on epidemiological indicators such as incidence and prevalence, and identify areas needing strengthening.

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Annex XLIII

Original: English

November 2012

REPORT OF THE MEETING OF THE OIE ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

Paris, 20–22 November 2012

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The OIE Working Group on Animal Production Food Safety (the Working Group) held its twelfth meeting at the OIE Headquarters from 20 to 22 November 2012.

The members of the Working Group and other participants are listed at Annex I. The adopted agenda is provided at Annex II.

Dr Alejandro Thiermann (President of the OIE Terrestrial Animal Health Standards Commission, Code Commission), on behalf of Dr Bernard Vallat (OIE Director General) welcomed the members of the Working Group to this meeting. He noted that the Working Group membership had changed slightly since the 2011 meeting with the departure of Mr Alan Randell and Mr Michael Scannell and the arrival of a new member, Dr Koen Van Dyck. He reminded the Working Group that their main objective should be to serve as a permanent advisory body to the OIE in terms of direction and approach for standards on animal production food safety. This Working Group has already been instrumental in facilitating the collaboration and complementarity of the work of the OIE and the Codex. He noted that the approach being taken by the OIE and the Codex on the work on trichinellosis demonstrated the way to work together on this and future standard setting work relevant to both organisations. Dr Thiermann requested that the Working Group examine the relevant documents and provide guidance as to the approach to take when developing future standards on the control of *Salmonella* spp. in food-producing animals other than poultry.

Dr Vallat met with the Working Group for a discussion later on the meeting. Dr Vallat welcomed members and thanked them for their support in this important area of work. He stated that the OIE appreciates the work of the Group that is critical to the OIE achieving its objective of reducing risks to human health due to hazards arising from animal products.

Collaboration between the OIE and the Codex Alimentarius Commission

Dr Vallat welcomed the creation of the Codex electronic Working Group (eWG) on Codex/ OIE Cooperation which will provide another opportunity to strengthen cooperation between the OIE and Codex. Dr Vallat acknowledged that the development of common standards was not feasible and that work to systematically cross reference each other's standards will be more achievable. Dr Vallat welcomed inputs from the Working Group on this topic. Dr Vallat supported the initiative to continue to invite chairs or relevant experts of a Codex Working Group to OIE *ad hoc* Groups, when relevant, and considered this an important means of ensuring alignment of relevant standard development work between the two organisations.

Collaboration at the national level

Regarding the importance of collaboration at the national level, Dr Vallat noted that at a meeting of the FAO/OIE/WHO Tripartite Strategy meeting, one of the recommendations was to request that OIE focal points for animal production food safety participate in INFOSAN activities and vice-versa. Dr Vallat informed the Working Group that OIE Delegates had been informed of this recommendation and asked to consider this request, which he saw as a good step to improve coordination at the national level.

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Future standard setting for animal production food safety

Dr Vallat welcomed the Working Group's recommendation that the OIE should only consider standard development on *Salmonella* in food-producing animals other than poultry, if Codex initiates new work on this topic so as to ensure a whole of food chain approach. Dr Vallat reiterated his support of the Working Group's proposal that the OIE should continue to consider developing guidance for relevant foodborne pathogens that do not cause clinical disease in animals but can be controlled at the on-farm level. He noted that this area of work can be a challenge for the OIE as it is necessary to distinguish trade risks and management of public health risks associated with such pathogens.

Antimicrobial resistance

Dr Vallat highlighted the growing debate surrounding the issue of antibiotic resistance and that the OIE is committed to working closely with Codex on standard setting work on this topic. He informed the Working Group that the OIE would host a Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals in Paris (France) on 13–15 March 2013. He noted the challenges arising from the imbalance of approaches being taken in developed and developing countries to regulate the use of antimicrobials. Dr Vallat emphasised the importance of providing resources to developing countries to develop and implement appropriate legislation, as well as veterinary education and capacity building of veterinary services, to prevent the development of antimicrobial resistance.

One Health

Dr Vallat informed the Working Group that the OIE is currently developing a PVS One Health Tool as part of the OIE PVS Pathway. The aim of such a mission is to review a country's Veterinary Service activities that specifically focus on collaboration and coordination with public health and other relevant partners, where the achievement of public health outcomes is a major objective. To date, a pilot evaluation has been made in three countries. Fourteen of the 46 critical competencies of the OIE PVS Tool have been determined to have the most direct link, through the collaborative efforts of the Veterinary Service, to public health outcomes. The OIE is also in discussion with WHO to develop a common approach to good governance that will ensure no duplication or gaps between the PVS One Health Tool and the WHO International Health Regulations. Dr Vallat noted that within the OIE mandate public health includes all zoonotic public health risks not just animal production food safety.

1. Update on CAC / FAO / WHO activities

1.1. CAC

Dr Annamaria Bruno provided an update on the work of CAC. Detailed information is provided in Annex III.

1.2. FAO

Dr Katinka de Balogh provided an update on the work of FAO. Detailed information is provided in Annex IV.

1.3. WHO

Dr Elizabeth Mumford, representing the WHO Department of Food Safety and Zoonoses, joined the meeting for this agenda item and provided an update on the work of WHO. Detailed information is provided in Annex V.

The Working Group encouraged the Director General of the OIE to continue to support communication and collaboration between the Secretariats of OIE and Codex, and the relevant units at the FAO and WHO, to ensure close co-ordination of the relevant work of these organisations.

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2. Cooperation between OIE and CAC: a CCGP electronic Working Group on Codex/OIE Cooperation

Dr Gillian Mylrea (Deputy Head, OIE International Trade Department) reported that at the 27th Session of the Codex Committee on General Principles (CCGP), held in Paris in April 2012, the CCGP decided to establish an electronic working group (eWG), to be hosted by Canada, with the following mandate:

'Reaffirming the commitment to collaboration in the development of standards of mutual interest, respecting the mandates and procedures of Codex Alimentarius and OIE, including a commitment to an open, transparent and inclusive process, the working group will:

- propose guidance to better take into account relevant work that has been undertaken or is in progress by each organization; and
- identify means to consistently reference each other's standards and guidance, as appropriate.'

Dr Mylrea informed the Working Group that the OIE will participate in this eWG and that the OIE has offered logistic support for a physical working group, with the same mandate, prior to the next session of the CCGP (April 2014).

The OIE International Trade Department is preparing a paper for submission to the eWG and had requested that the Working Group provide general guidance on this topic.

The Working Group noted that the regular participation in each other's standard setting work has helped to improve the coverage by official standards of the whole food production continuum and to avoid gaps, duplications and potential contradictions in the standards and guidelines of the two organisations. This is particularly evident in the recent work by both organisations on *Salmonella* in poultry and the current work on *Trichinella*, where a whole food chain approach has been taken.

Dr Mylrea informed the Working Group that the recent meeting of the OIE *ad hoc* Group on Zoonotic Parasites included the two Co-chairs of the Codex Working Group on Guidelines for Control of Specific Zoonotic Parasites in Meat, who had been invited in response to a request that the OIE work in closer collaboration with the Codex on the development of this standard.

The Working Group recommended that such participation be considered as a model for future collaboration.

The Working Group made the following recommendations to the OIE for consideration by the eWG:

a) Cross-referencing standards of the OIE and CAC

The Working Group recognised that different approaches have been taken in the past regarding cross-referencing and they recommended that the eWG review existing OIE and Codex texts to ensure a consistent approach and to then consider some general guidance as to how to address this issue in the future. The Working Group acknowledged that the approach needed to maintain some flexibility depending on the specific standards under development and the expected users. The Working Group recommended that definitions also be aligned as much as possible.

b) Continued collaboration between OIE and Codex in the development of standards

In order to ensure the continuation of collaboration between the OIE and Codex, the OIE should:

i) continue the work of the Working Group;

ii) continue the exchange of information between OIE and CAC Secretariats;

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iii) continue to attend relevant Codex Committees and provide updates on relevant OIE activities;

iv) invite the Chairperson from the relevant Codex Working Group to OIE *ad hoc* groups, when addressing subject matter common to OIE and Codex.

c) Planning work for standard development

The Working Group noted that the OIE and the CAC have different mechanisms for planning standard development. Informally, the two organisations become aware of each other's work plans on standard development relevant to both organisations; however, there is no procedure to align these.

The Working Group noted that work plans and new activities are discussed by this Working Group each year when they meet. They recommended that special emphasis be put on this point at future meetings and to include it as a standard agenda item.

d) Coordination at the national level

The Working Group re-emphasised the importance of collaboration between OIE and Codex at the national level between OIE Delegates and focal points, and Codex contact points, in order to better co-ordinate the standard setting activities of the two organisations. Coordination at the regional and sub-regional level is also encouraged.

3. Zoonotic parasites

3.1. Chapters on Infection with *Trichinella* spp.

Dr Mylrea informed the Working Group that an expert *ad hoc* Group on Zoonotic Parasites, which included participation from the WHO, FAO and Codex, had updated the current OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) Chapter 8.13. on Trichinellosis with the objective of recommending control measures at the on-farm level to help prevent foodborne illness in humans.

The draft chapter provides recommendations for on-farm prevention of *Trichinella* infection in domestic pigs (*Sus scrofa domesticus*), and safe trade of meat and meat products derived from suids and equids. It provides for establishing a 'negligible risk compartment' in pigs kept under controlled management conditions on the basis of the clear and objective means of establishing this status. The articles dealing with international trade of meat and meat products of suids and equids include a cross reference to the relevant Codex Guidelines.

The draft chapter has undergone two rounds of consultation with OIE Members. The latest revision undertaken by the *ad hoc* Group, in July 2012, considered the comments of OIE Member Countries from the second round of consultation. This meeting also included the two Co-chairs of the Codex Working Group on Guidelines for Control of Specific Zoonotic Parasites in Meat, who had been invited in response to a request that the OIE work in closer collaboration with the Codex on the development of this standard. The participation of the Co-chairs provided a good opportunity for the OIE and Codex to work closely together on the development of respective standards on *Trichinella* and ensure alignment of risk-based recommendations while avoiding duplication of effort, overlap and gaps. The revised draft chapter was reviewed by the Code Commission at their September 2012 meeting and has been circulated to OIE Members as part of the Code Commission's September 2012 report.

The Working Group supported the proposed draft chapters.

Dr Steve Hathaway informed the Working Group of the discussion held at the 44th Session of the Codex Committee on Food Hygiene (CCFH), in November 2012, on the development of the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat and the proposal for an alternative pathway to achieving a negligible risk compartment for Infection with *Trichinella* spp. to that described in the revised OIE draft Chapter 8.13. This pathway would rely less on on-going verification of farms but would provide for on-going monitoring of a representative sample of slaughter pigs to confirm the status of the compartment.

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The Working Group recommended that the OIE National Delegates make appropriate contacts with Delegates to CCFH, on their review and comments on the OIE draft Chapter 8.13. The Working Group noted that external support can enhance such co-ordination in this and other relevant areas in many developing countries.

3.2. Chapters on *E. granulosus*, and *E. multilocularis*

Dr Mylrea informed the Working Group that an expert *ad hoc* Group on Zoonotic Parasites, which included participation from the WHO, FAO and Codex, had updated the current OIE *Terrestrial Code* Chapter 8.4. on Echinococcosis/hydatidosis and had proposed to develop two separate chapters, on *E. granulosus*, and *E. multilocularis*. The draft chapter was reviewed by the Code Commission at their September 2012 meeting and has been circulated to OIE Members as part of the Code Commission's September 2012 report.

The Working Group supported the proposed draft chapters.

4. OIE work on antimicrobial resistance in terrestrial animals

Dr François Diaz (OIE Scientific and Technical Department) joined the meeting for this agenda item and provided an update on current OIE activities relevant to the issue of antimicrobial resistance (AMR).

Dr Diaz informed the Working Group that the revised *Terrestrial Code* Chapters 6.7. and 6.8. had been adopted at the General Session in May 2012 and a revised Guideline on Laboratory Methodologies for bacterial antimicrobial susceptibility testing had been added to the latest edition of the *Terrestrial Manual*.

Dr Diaz provided an update on the work done by the *ad hoc* Group on Antimicrobial Resistance. He reported that, since the last meeting of the Working Group, the *ad hoc* Group met two times, from 12 to 14 December 2011 and from 2 to 4 July 2012 at the OIE Headquarters. At the December 2011 meeting, the Group reviewed and updated the *Terrestrial Code* Chapter 6.10. Risk assessment for antimicrobial resistance arising from the use of antimicrobial agents in animals. It also started to address the OIE Member Country comments received on the previously updated version of the *Terrestrial Code* Chapter 6.9. Responsible and prudent use of antimicrobial agents in veterinary medicine. At the July 2012 meeting, the Group considered the Member Countries' comments on Chapter 6.9. The Group also started to update the List of Antimicrobials of Veterinary Importance. Finally it proposed the inclusion of new concepts in the Glossary of the *Terrestrial Code*. The next meeting of this Group will take place in January 2013. The main objectives of this meeting will be to address Member Countries' comments and finalise the updating of Chapter 6.10. and complete the work on the List.

Dr Diaz informed the Working Group that the OIE was still working in collaboration with WHO and FAO on the topic of AMR, which was a priority in the OIE/FAO/WHO Tripartite Strategy. In addition, the Scientific and Technical Department of the OIE has nearly completed a second cycle of training for OIE National Focal Points for Veterinary Products with an emphasis on the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) and AMR.

Dr Diaz also informed the Working Group that the OIE would organise a Global Conference on the Responsible and Prudent Use of Antimicrobials for Animals, 'International Solidarity to Fight against Antimicrobial Resistance', in Paris (France) from 13 to 15 March 2013 (http://www.oie.int/eng/A_AMR2013/introduction.htm). In the framework of this conference, the OIE had sent out a questionnaire to OIE Member Countries on monitoring of the quantities of antimicrobial agents used in animals. The results of the survey would be analysed and presented at this OIE Conference.

Dr Diaz presented the new dedicated place for AMR on the OIE website (http://www.oie.int/en/our-scientific-expertise/veterinaryproducts/antimicrobials/). Finally he drew to the Working Group's attention the recently published Volume 31(1) of the OIE *Scientific and Technical Review* on 'Antimicrobial resistance in animal and public health'.

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Regarding the draft Chapter 6.10. Risk Analysis for Antimicrobial Resistance Arising from the Use of Antimicrobial Agents in Animals, currently under review, the Working Group noted that Article 6.10.2. on the analysis of risks to human health uses the OIE risk analysis framework rather than the Codex framework. The Working Group recommended that the *ad hoc* Group, who will meet in January 2013 to review the draft chapter, take into account if possible the 'Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance' (CAC/GL 77-2011), and include a specific reference to this text in the draft chapter.

5. OIE work on antimicrobial resistance in aquatic animals

Dr Mylrea updated the Working Group on activities related to antimicrobial resistance in aquatic animals. She informed the Group that the *Aquatic Animal Health Code* (*Aquatic Code*) Chapter 6.4. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Chapter 6.5. Development and harmonisation of national antimicrobial resistance surveillance and monitoring had been adopted in May 2012. She informed the Working Group that the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals are developing a chapter on risk analysis for antimicrobial resistance in aquaculture to be included in Section 6 of the *Aquatic Code*.

The Working Group noted this work and that the Codex *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77- 2011), also covered both terrestrial and aquatic animals.

6. OIE work on veterinary education

Dr Mylrea updated the Working Group regarding the OIE's work on veterinary education, with particular reference to the 'OIE recommendations on the Competencies of graduating veterinarians ('Day 1 graduates') to assure National Veterinary Services of quality'. She noted that this document is available on the OIE internet site at:

http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/Vet_Edu_AHG/DAY_1/DAYONE-B-ang-vC.pdf

Dr Mylrea also informed the Working Group that the *ad hoc* Group on Veterinary Education met in July 2012 to develop a draft Model Core Curriculum, which provides for graduates to possess the Day 1 competencies recommended by the OIE.

The Working Group supported the OIE work in the area of veterinary education and agreed that the draft Model Core Curriculum document covered the essential core curriculum relevant to the training of a veterinarian, including food safety and food hygiene.

7. OIE PVS Tools: for the Evaluation of Veterinary Services and Aquatic Animal Health Services

Dr Mylrea updated the Working Group on recent revisions to the *PVS Tool* (2013 edition). She noted that the critical competency (CC) on food safety (II-8) had been amended to add a third point to this CC to address the standards of food producing premises, as follows:

'II-8 C. Regulation, authorisation and inspection of establishments for the production, processing and distribution of food of animal origin. The authority and capability of the VS to establish and enforce sanitary standards for establishments that produce, process and distribute food of animal origin.'

The Working Group noted that the text for this CC could be improved by including reference to a risk based approach to ensure those pathogens not detected at *ante-mortem* and *post-mortem* inspection are addressed, as many foodborne pathogens are not detected at the macroscopic level, e.g. STEC, *Salmonella*, *Campylobacter*.

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The Working Group recommended that for any future revisions of the PVS Tool, a member of the Working Group or a relevant expert in animal production food safety, be included in the *ad hoc* Group or be given the opportunity to provide input on relevant CCs.

8. Future standard setting for animal production food safety

8.1. Literature review on the control of *Salmonella* spp. in food-producing animals other than poultry

At the 2010 meeting, the Working Group discussed the need for and feasibility of developing OIE advice on the control of *Salmonella* spp. in food-producing animals other than poultry (i.e. pigs, cattle, small ruminants) with the purpose of reducing foodborne illness. In this regard the Working Group requested that the OIE undertake a review of the scientific literature on these pathogens with an emphasis on the feasibility of applying measures at the production level (farm-level) to reduce the incidence. Dr Rob Davies (OIE Reference Laboratory for Salmonellosis, United Kingdom) and Dr Antonia Ricci (OIE Reference Laboratory for Salmonellosis, Italy) were invited to undertake this review.

At their 2011 meeting, the Working Group reviewed the draft prepared for that meeting and requested that the authors expand the section on the feasibility of applying measures at the production level (farm-level) to reduce the incidence of *Salmonella* spp. in intensive pigs, to assess likely public health outcomes of applying such measures, and to provide more information on the prevalence of foodborne salmonellosis in humans from food-producing animals other than poultry.

At this meeting, the Working Group reviewed the updated literature review. The Working Group was impressed with the revised paper and requested the Trade Department to thank the authors for all their work in developing the document. The Working Group also supported the suggestion that OIE have the paper peer reviewed and then published on the OIE website in English, Spanish and French. The Working Group assumed that the peer review would ensure that the literature review took into account the global situation.

When the paper is ready for publication, the Trade Department will send a copy to the FAO, WHO and Codex bringing the paper to their attention.

After much discussion on next steps OIE may take on this subject, it was agreed that given the need for a whole food chain approach to *Salmonella* risk management in food-producing animals other than poultry, and the diversity of global animal production systems; unilateral advancement of this work in OIE alone is unlikely to significantly improve salmonella risk management animals other than poultry.

Rather, the Working Group agreed that should Codex initiate new work on *Salmonella* spp. in food-producing animals other than poultry, then the Working Group would encourage OIE participation to ensure a whole of food chain approach.

8.2. Literature review on the control of verotoxigenic *Escherichia coli* (VTEC) in food-producing animals

At the 2010 meeting, the Working Group discussed the need for and feasibility of developing OIE advice on the control of verotoxigenic *Escherichia coli* (VTEC/STEC) in food-producing animals with the purpose of reducing foodborne illness. In this regard the Working Group requested that a review of the scientific literature be undertaken on this pathogen. Dr John Morris Fairbrother, OIE Reference Laboratory for *Escherichia coli* (Canada), was invited to undertake this review.

At their 2011 meeting the Working Group reviewed the abridged version provided for that meeting and requested that the authors provide more emphasis on the availability and efficacy of applying measures at the production level (farm-level) to reduce the incidence of verotoxigenic *Escherichia coli* (VTEC) in livestock, and to assess the likely public health outcomes of applying such measures.

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Unfortunately, the authors were unable to finalise the review in time for consideration by the Working Group at this meeting. The Working Group looked forward to receiving the amended literature review in the near future.

Given that prevention and control of contamination of meat and other animal products with pathogens of enteric origin has emerged as a priority in food safety, the Working Group agreed that the OIE and Codex should maintain an active dialogue through this Working Group concerning potential standard development in this area e.g. Salmonella, STECs.

9. Report of the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents

Dr Mylrea informed the Working Group that an expert *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents had met in July 2012 to review the OIE list of diseases for terrestrial animals against the revised criteria for listing. She noted that the *ad hoc* Group had proposed to delist porcine cysticercosis (*Taenia solium*). However, the Code Commission considered this to be a major neglected zoonosis and had invited Member Countries to provide their comments on this proposal.

Dr de Balogh noted that FAO considers porcine cysticercosis to be a significant public health concern particularly in developing countries. Dr Bruno also noted that the report of the FAO/WHO Expert Meeting on Foodborne Parasites–Multicriteria based ranking for risk management, ranked *Taenia solium* (pork) as the foodborne parasite of most importance with respect to public health, from a list of 24 parasites.

The Working Group recommended that given the public health significance of this disease, this proposal should be carefully reassessed. The Working Group recommended that, should the disease be delisted, a guidance document should be developed for Members to assist them in controlling this disease at the on-farm level.

10. Transmission of chemical contaminants through feed

The Working Group noted that Codex has developed a number of texts relevant to chemical contaminants in animal feed (e.g. dioxins, aflatoxins). It should be noted that these texts address the food safety aspects linked to animal feed, and not animal health concerns.

The Working Group noted that Codex also has some on-going work on this topic, including the Codex Task Force on Animal Feeding who are developing 'Guidelines on application of risk assessment for feed' and 'Guidance for use by governments in prioritizing the national feed hazards', and the Codex Committee on Contaminants in Food (CCCF) is developing Code of Practice for Weed Control to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Food and Feed. In addition the CCCF is developing a discussion paper on management practices to reduce exposure of animals to pyrrolizidine alkaloids (PAs); to reduce exposure of food-producing animals to PA-containing plants; and to reduce presence of PAs in commodities.

Given that Codex has already undertaken significant work on this topic and that the current *Terrestrial Code* and the *Aquatic Code* include chapters on hazards in animal feed, the Working Group recommended that the OIE not undertake any further work on this topic (chemical non biological contaminants) at this time but continue to contribute actively to the Codex work programme.

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11. Work programme for 2013

The Working Group noted that a continuing theme arising from discussions of all agenda items was the need for a whole of food chain risk-based approach to the management of zoonotic hazards in food. The Working Group re-affirmed that collaboration between the OIE and Codex is essential to reflect this principle in international standards.

The on-going developments with regard to the 'One-Health' approach and the discussions on enhancing collaboration between animal health, public health and environmental health systems at the international, regional and national levels provides new opportunities to enhance this whole food chain approach.

The Working Group amended the work programme for 2013 which is presented at Annex VI.

12. Next meeting

To be confirmed.

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Annex I

MEETING OF THE OIE ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

Paris, 20–22 November 2012

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Annex II

MEETING OF THE OIE ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

Paris, 20–22 November 2012

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Adopted agenda

Welcome from the OIE Director General

Adoption of the agenda

Report of the previous Working Group meeting

1. Update on CAC / FAO / WHO activities
   - 1.1. Codex
   - 1.2. FAO
   - 1.3. WHO
2. Cooperation between OIE and CAC: a CCGP electronic Working Group on Codex/OIE Cooperation
3. Zoonotic parasites
   - 3.1. Chapter on Infection with *Trichinella* spp.
   - 3.2. Chapters on E. *granulosus*, and E. *multilocularis*
4. OIE work on antimicrobial resistance in terrestrial animals
5. OIE work on antimicrobial resistance in aquatic animals
6. OIE work on Veterinary Education
7. OIE PVS Tools: for the Evaluation of Veterinary Services and Aquatic Animal Health Services
8. Future standard setting for animal production food safety
   - 8.1. Literature review on the control of *Salmonella* spp. in food-producing animals other than poultry
   - 8.2. Literature review on the control of verotoxigenic *Escherichia coli* (VTEC) in food-producing animals
9. Report of the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents
10. Transmission of chemical contaminants through feed
11. Work programme for 2013
12. Next meeting

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Annex III

ACTIVITIES OF THE CODEX ALIMENTARIUS COMMISSION CODEX SESSIONS SINCE THE LAST MEETING OF THE OIE APFSWG (15-17 NOVEMBER 2011)

In the period 1 November 2011 - 15 October 2012, 17 sessions of the Code Alimentarius Commission and its subsidiary bodies have been held. Among these sessions, those relevant to the work of the APFSWG, are: the 35th Session of the Codex Alimentarius Commission (CAC), Rome, Italy, 2-7 July 2012; the 43rd Session of the Committee on Food Hygiene (CCFH), Miami, United States of America, 5-9 December 2011; the 6th Session of the ad hoc International Task Force on Animal Feeding (TFAF), Berne, Switzerland 20-24 February 2012; the 6th Session of the Committee on Contaminants in Foods (CCCF), Maastricht, the Netherlands, 26-30 March 2012; the 27th Session of the Committee on General Principles (CCGP), Paris, France 2-6 April 2012; the 20th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), San Juan, Puerto Rico, 7-11 May 2012; 21-25 March 2011; and the 32nd Session of the Committee on Fish and Fishery Products (CCFFP), Bali, Indonesia, 1-5 October 2012.

In addition, in the reporting period have been held the sessions of the FAO/WHO Coordinating Committees for the North America and the South-West Pacific (CCNASWP), Madang, Papua New Guinea, 19-22 September 2012; and for Europe (CCEURO), Batumi, Georgia, 25-28 September 2012.

In particular, the APFSWG may wish to note the following:

The 35th CAC, among others, adopted 18 new or revised Codex standards or related texts and many new or revised provisions for additives and MRLs for pesticides and veterinary drugs (see **Appendix I**), and approved a number of new work proposals (see **Appendix II**). Among the new and revised standards adopted by the CAC, the following are particularly relevant to the APFSWG: MRLs for ractopamine (cattle and pig tissues); for narasin (cattle tissues); for amoxicillin (cattle, sheep and pig tissues and cattle and sheep milk); and for monensin (cattle liver). The sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (C, Annex B of CAC/GL 71-2009); and the Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food.

The 35th CAC also adopted a number of maximum residue limits (MRLs) for pesticides in products of animal origin and in animal feed. All these texts are available on the Codex website: www.codexalimentarius.org , including the update database for MRLs of veterinary drugs: http://www.codexalimentarius.org/standards/veterinary-drugs-mrls/en/ and the reports of the above sessions are available on the FAO ftp server at: ftp://ftp.fao.org/codex/reports/reports_2012 (for sessions up to the 35th CAC) and ftp://ftp.fao.org/codex/reports/reports_2013 (for sessions held after the 35th CAC).

The 35th CAC adopted the revision of the Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene and the Risk Analysis Principles Applied by the Codex Committee on Contaminants in Foods and the revision of the definition of "contaminant". The revision of these texts aims at addressing their applicability to animal feed as it may impact on human health. The 35th CAC also adopted the revision of the Risk Analysis Principles Applied by the CCRVDF and of the Risk Assessment Policy for Residues of Veterinary Drugs in Foods.

Among the new work approved by the 35th CAC, the following are particularly relevant to the APFSWG: Code of Practice for Weed Control to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Food and Feed (to be developed by the CCCF); and Risk Management Recommendations for Residues of Veterinary Drugs for which no ADI and/or MRLs has been recommended by JECFA due to Specific Human Health Concerns (to be developed by the CCRVDF). In addition the 35th CAC has approved the priority list of veterinary drugs for evaluation or re-evaluation by JECFA, which includes: apramycin; derquantel; emamectin benzoate; gentian violet; lasalocid; monepantel; phenylpyrazole; and zylpaterol hydrochloride. The 35th CAC considered the MRLs for bovine somatotropins (bSTs) and agreed to request JECFA to re-evaluate bSTs and that the full report of JECFA evaluation would be considered by the CCRVDF.

The 35th CAC also considered the implementation of the Strategic Plan 2008-2013 of the Codex Alimentarius Commission and the draft Strategic Plan 2014-2018, and agreed on the process to be followed for its completion for adoption by the 36th Session of the Commission.

With regard to the sessions of the other committees/task force, the following is an updated on matters particular relevant to the APFSWG:

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The **43rd CCFH** continued work on the Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods and the Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella spiralis* and *Cysticercus bovis*. With regard to the latter, the CCFH noted that collaboration with OIE was necessary to ensure that OIE and Codex cover, in an integrated way, the risk reduction measures along the food chain (i.e. pre- and post-harvest). The Committee noted that mechanisms were in place to allow coordination of OIE and Codex work, such as participation of OIE in the meetings of the Committee and in electronic / physical working groups and that the Codex Secretariat, FAO and WHO had been invited by OIE to participate in the ad hoc Expert Group on zoonotic parasites. The Committee also noted that coordination of provision of inputs to Codex and OIE work at national level was necessary to ensure an integrated approach to this work.

The **6th TFAF** (the first meeting of the new Task Force on Animal Feeding) made substantial progress on the development of the Guidelines on Application of Risk Assessment for Feed, which were forwarded to the 35th CAC for adoption as a draft. The TFAF agreed to revise the scope of its second document to focus on the criteria for prioritization of hazards in feed and guidance for governments on how to use these criteria and to request an electronic working group to prepare a revised document for circulation for comments and consideration at its next session. It is expected that the TFAF will complete its work at its next session to be held in Berne (Switzerland) from 4 to 8 February 2013.

At the **27th CCGP** the Observer from OIE withdrew the proposal for the development of joint standards, to improve harmonization of standards on common topics, such as traceability, antimicrobial resistance, salmonellosis and certification in view of the concerns expressed by Codex Members about the approach, in the light of differences between the standard-setting procedures of the two Organisations. The CCGP recognized the importance of the collaboration between Codex and OIE and agreed to establish an electronic working group, chaired by Canada, with the following mandate:

> "Reaffirming the commitment to collaboration in the development of standards of mutual interest, respecting the mandates and procedures of Codex Alimentarius and OIE, including a commitment to an open, transparent and inclusive process, the working group will propose guidance to better take into account relevant work that has been undertaken or is in progress by each organization and identify means to consistently reference each other's standards and guidance, as appropriate."

The CCGP further agreed that a physical working group, with the same mandate, would be held prior to the next session of the CCGP and the Committee welcomed the kind offer of OIE to provide logistical support to the meeting. The 28th Session of the CCGP is tentatively scheduled in the spring of 2014 in Paris.

The **20th CCRVDF** forwarded for adoption to the Commission several Maximum Residues Limits (MRLs) for Veterinary Drugs: narasin (in cattle tissues) amoxicillin in several tissues; monensin (in cattle's liver); and the Proposed draft Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (Table C, Annex B of CAC/GL 71-2009). It finalized the revision of the Risk Analysis Principles applied by the CCRVDF and the Risk Assessment Policy for Residues of Veterinary Drugs in Foods. It proceeded with work on Proposed draft Guidelines on Performance Characteristics for Multi-residues Methods (Appendix to CAC/GL 71-2009), established a Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation by JECFA and proposed new work on Risk Management Recommendations for Residues of Veterinary Drugs for which no ADI and/or MRLs has been recommended by JECFA due to Specific Human Health Concerns.

The **32nd CCFFP** forwarded for adoption to the Commission several standards for fish and fish products, including the Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish and for Fresh/Live and Frozen Abalone (*Haliotis* spp). The Committee also finalised work on the Confirmatory Methods for Marine Biotoxins in the Standard for Live and Raw Bivalve Molluscs and proposed new work on a Code of Practice for Fish Sauce.

The **44th CCFH** forwarded for adoption to the Commission the revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods and agreed to continue work on the Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella* spp. and *Cysticercus bovis* and to consider a discussion paper on occurrence and control of parasites in foods at its next session. With regard to the work on *Trichinella* spp. the Committee noted the need for Members to coordinate their position at country-level with national delegates to OIE to further elaborate the guidelines and highlighted the importance to continue strengthening the collaboration with OIE without overlapping with each other's responsibilities. It further noted that strengthened collaboration with OIE would ensure consistency of Codex and OIE texts and allow countries to implement consistently control measures along the entire food chain.

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Forthcoming CODEX Meetings (relevant to the OIE APFSWG)

The 7th TFAF, Berne, Switzerland, 4 to 8 February 2013. The provisional agenda is available at: http://www.codexalimentarius.org/download/report/792/af07_01e.pdf

The 20th CCFICS will be held in Chiang Mai (Thailand) from 18 to 22 February 2013. The Committee will continue its work on the elaboration of the Principles and Guidelines for National Food Control Systems. The Committee will also consider discussion papers addressing: the burden of multiple questionnaires directed at exporting countries; monitoring regulatory performance of national food control systems and the need for further guidance on food safety emergencies.

The 36th CAC will be held in Rome, Italy, from 1 to 5 July 2013. The provisional agenda will be posted on the Codex website: www.codealimentarius.org/meetings-report.

The 21st CCRVDF will be held in the United States of America from 26 to 30 August 2013.

The provisional agendas of the 20th CCFICS, 36th CAC and 21st CCRVDF will be posted, as soon as available, on the Codex website: www.codealimentarius.org/meetings-report.

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Appendix I

LISTS OF STANDARDS AND RELATED TEXTS ADOPTED BY THE THIRTY-FIFTH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Part 1 – Standards and Related Texts Adopted at Step 8

Standards and Related Texts	Reference	Status
Food additive provisions of the *General Standard for Food Additives* (GSFA),	REP12/FA Appendix VI	adopted with amendments
Revision of the *Standard for Food Grade Salt* (CODEX STAN 150-1985)	REP12/FA Appendix XI	adopted
Maximum Level for Melamine in Liquid Infant Formula (ready to consume)	REP12/CF Appendix V	adopted
Maximum Residue Limits for Pesticides	REP12/PR Appendix II	adopted
Revision to the Codex Classification of Food and Animal Feed (fruit commodity groups)	REP12/PR Appendix VIII	adopted
Principles and Guidance for the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups (including Table 1: Examples of the selection of representative commodities - fruit commodity groups)	REP12/PR Appendix XI	adopted
MRLs for narasin (cattle tissues)	REP12/RVDF Appendix III	adopted
MRLs for ractopamine (cattle and pig tissues: muscle, liver, kidney and fat)	ALINORM 08/31/31 Appendix II	adopted
Revision of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) concerning a new definition of "nutrient reference values"	REP12/FL Appendix IV	adopted
Amendment to the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* (CAC/GL 32-1999): use of ethylene for ripening of fruit	REP12/FL Appendix VI	adopted

Part 2 – Standards and Related Texts Adopted at Step 5/8 (with omission of Step 6 and 7)

Standards and Related Texts	Reference	Status
Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food	REP12/FH Appendix III	adopted with amendments
Annex on Melons to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003)	REP12/FH Appendix IV	adopted
Food additive provisions of the *General Standard for Food Additives* (GSFA)	REP12/FA Appendix VI	adopted with amendments
Amendments to the *International numbering system* (INS) for food additives	REP12/FA Appendix XII	adopted with amendments
Specifications for the identity and purity of food additives arising from the 74th JECFA meeting	REP12/FA Appendix XIII (Part 1)	adopted
Maximum Level for Total Aflatoxins in Dried Figs, including Sampling Plan	REP12/CF Appendix VI	adopted
Maximum Residue Limits for Pesticides	REP12/PR Appendix III	adopted

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Appendix I (contd)

MRLs for amoxicillin (cattle, sheep and pig tissues and cattle and sheep milk) and monensin (cattle liver)	REP12/RVDF Appendix IV	adopted
Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Aquatic Origin (C, Annex B of CAC/GL 71-2009)	REP12/RVDF Appendix VIII	adopted
Revision of the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) concerning a new definition for "non-addition claim", conditions for free of salt claims, amendments to the section on comparative claims and conditions for non-addition of sugars claims	REP12/FL Appendix II	adopted
Revision of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) concerning provisions for mandatory nutrition labelling	REP12/FL Appendix V	adopted

Part 3 – Standards and Related Texts Adopted at Step 5 of the Accelerated Procedure

Standards and Related Texts	Reference	Status
Amendment to the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* (CAC/GL 32-1999) concerning inclusion of new substances	REP12/FL Appendix VII	adopted

Part 4 – Other Standards and Related Texts Submitted for Adoption

Standards and Related Texts	Reference	Status
Amendment to the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*	REP12/FH Appendix II	adopted with amendments
Methods of Analysis in Codex Standards at different steps, including methods of analysis for food grade salt	REP12/MAS Appendix II	adopted with amendments
Revision of the names and descriptors of food categories 16.0 and 12.6.1 of the GSFA	REP12/FA Appendix X	adopted
Revision of the Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals	REP12/CF Appendix III	adopted with amendments
Regional standard for Fermented Soybean Paste (CODEX STAN 298R-2009) - provision for monopotassium tartrate (INS 336(i))	REP11/ASIA para. 10	adopted

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Appendix II

LIST OF DRAFT STANDARDS AND RELATED TEXTS APPROVED AS NEW WORK BY THE THIRTY-FIFTH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Responsible Body	Standard and Related Texts	Reference	Job Code
CCFH	Revision of the *Code of Hygienic Practice for Spices and Dried Aromatic Plants*	REP12/FH Appendix VII	N01-2012
CCFH	Annex on berries to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003)	REP12/FH Appendix VIII	N02-2012
CCCF	Code of Practice for Weed Control to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Food and Feed	REP12/CF Appendix VII	N03-2012
CCCF	Revision of the Maximum Levels for Lead in Fruit Juices, Milks and Secondary Milk Products, Infant Formula, Canned Fruits and Vegetables, Fruits and Cereal Grains (except buckwheat, cañihua and quinoa) in the *General Standard for Contaminants and Toxins in Food and Feed*	REP12/CF Appendix VIII	N04-2012
CCCF	Annex for Prevention and Reduction of Aflatoxins and Ochratoxin A in Sorghum to the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003)	REP12/CF Appendix IX	N05-2012
CCCF	Code of Practice for the Prevention and Reduction of Ochratoxin A contamination in Cocoa	REP12/CF Appendix X	N06-2012
CCCF	Code of Practice to Reduce the Presence of Hydrocyanic Acid in Cassava and Cassava Products	REP12/CF para. 165	N07-2012
CCCF	Maximum Levels for hydrocyanic acid in cassava and cassava products	REP12/CF para. 165	N08-2012
CCCF	Levels for Radionuclides in Food	REP12/CF para. 169	N09-2012
CCPR	Priority List for the Establishment of MRLs for Pesticides	REP12/PR Appendix XIII	ongoing
CCRVDF	Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation by JECFA	REP12/RDVF Appendix IX Part A and B	ongoing
CCRVDF	Risk Management Recommendations for Residues of Veterinary Drugs for which no ADI and/or MRLs has been recommended by JECFA due to Specific Human Health Concerns	REP12/RDVF Appendix X	N10-2012
CCNEA	Regional Standard for Date Paste	REP11/NEA para. 92 CX/CAC 12/35/9-Add.1 Rev. 1	N11-2012

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Annex IV

ACTIVITIES OF THE FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Many of the activities conducted by the Animal Health Service (AGAH) of FAO related to Veterinary Public Health where closely linked to further developing different aspects of the One Health approach. This approach that initially was developed to address emerging zoonotic and other high impact diseases is gradually shifting to also encompass endemic (zoonotic) diseases and, in recent times, its value for addressing food safety issues has been recognized. FAO as part of the FAO/OIE/WHO Tripartite has also been addressing the ecosystems component of the One Health concept in addition the animal health domain. The Animal Health Service together with the section in FAO dealing with food safety and quality have cooperated in various aspects linked to animal production food safety. Over 2012 many of the activities that had been initiated during 2011 have been further developed or brought to completion.

Antimicrobial resistance

FAO is supporting national capacities for integrated foodborne pathogen (*Salmonella spp., E. coli, Campylobacter spp. & Enterococcus spp*.) and AMR surveillance in a number of countries. These have mostly been done in collaboration with the WHO. Recently a project in Kenya was completed, which generated data on foodborne pathogen and AMR prevalence in the beef, pork and poultry value chains. New projects are being initiated in Cambodia, Vietnam (aquaculture) and India with possibility of another project in Nigeria. These projects mirror the approach taken in the completed project in Kenya and the expected outcomes are the establishment of inter-agency task forces on AMR to implement policy priorities, establishment of national surveillance programmes on priority foodborne pathogens and AMR, antimicrobials usage monitoring programmes; as well as the implementation of national policies and best practices by meat value chain operators/actors to address emerging issues.

Guidance for value chain operators on appropriate use of veterinary inputs in animal production. This is being developed to address veterinary residues in products of animal origin and the risks of AMR development arising from inappropriate usage of antimicrobial agents in animal production. The material will be disseminated directly to small holder livestock keepers, especially in countries where activities mentioned before are being undertaken. FAO has also commissioned under a letter of agreement, an innovative approach, targeting rural and peri-urban small holder livestock keepers, which uses established TV programmes and SMS through mobile phones, to dissemination of good practice guidance to promote prudent and responsible usage of veterinary inputs in animal production.

Guidance on risk based official veterinary control of meat hygiene/safety for developing country is being developed and implemented. This is intended to provide national competent authorities with risk based decision making tools to ensure more risk based approach to meat inspection and hygiene, which addresses priority zoonotic and foodborne diseases and supports the achievement of national food safety objectives. Draft guidance will be pilot tested in at least 3 countries in 2013 and will be finalized thereafter for dissemination to other countries. FAO is supporting the strengthening of official veterinary controls in abattoirs as there is a need to improve the content and utility of existing guidance to address contemporary meat hygiene and food safety concerns, development of appropriate guidance on risk analysis and risk based approaches to inspection and hygiene, development of guidance and tools for animal and zoonotic disease surveillance and reporting in animal slaughter establishments; and development of laboratory capacities for detection and diagnosis of priority foodborne pathogens and zoonotic diseases. FAO VPH unit has developed appropriate activities to address issues in the next biennium.

FAO veterinary public health (VPH) continuing professional development (CPD) project - includes a food safety stream with more than 10 modules/lessons under the stream. The CPD initiative is aimed at developing and enhancing the professional competences of veterinarians and veterinary para professionals working in VPH and food safety and is being piloted in Kenya, Tanzania, Rwanda, Burundi and Uganda. Training materials have been developed by national institutions (vet faculties) and will be peer reviewed by partner institutions in developing and developed countries, with a view to finalization and implementation of CPD courses by the end of 2013;

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The Animal Production Service of FAO has prepared a 'Quality Assurance Manual for Microbiology in Animal Feed Analysis Laboratories'. The manual will be available for distribution during early 2013. It describes procedures for detection and isolation of microbiological agents which may be found in animal feeds. The Quality Management System is also described in this manual, which is based on ISO/IEC 17025:2005 principles and EA-04/10 'Accreditation for Microbiological Laboratories' and is intended to help laboratory personnel maintain the standards expected while providing a consistent, reliable, efficient and professional service with the level of quality required and expected by the laboratory's customers.

An International Workshop on the Use of Antimicrobials in Livestock Production and Antimicrobial Resistance in the Asia–Pacific Region was held in Negombo, Sri Lanka, on 22–23 October 2012 by FAO in conjunction with the 36th Session of the Animal Production and Health Commission for Asia (APHCA)..

The epidemiology and impact of antimicrobial resistance (AMR) and the links between antimicrobial use (AMU) in livestock and AMR in humans were discussed and APHCA delegates presented short country reports on AMU and AMR in their respective countries. Greater attention to AMU and AMR needs to be paid by animal health authorities in the Asia–Pacific region as there is a wide variation in the awareness of and capacity to manage the risks from AMR across APHCA member countries. There is a need for establishing National Task Forces on Antimicrobials that are multidisciplinary and cross-sectoral to provide a forum to lead policy development and support action on AMU and AMR; improve awareness at different levels (including farmers and farmer organizations; veterinarians, paraveterinarians, veterinary faculty staff members; policy-makers; consumers and civil society) and develop, review and improve practical legislation and regulatory frameworks. Furthermore, the monitoring and surveillance of AMU and AMR needs to be undertaken and data collected on AMU (e.g. types and of volume of antimicrobials used, purpose of use). Alternatives to AMU, particularly improved infection control, good husbandry practices, and farm biosecurity are further key issues that need to be further explored. In conclusion, AMU is not just a technical issue and required consideration of social, economic, environmental, ethical and policy factors. Delegates at the meeting recognized the need for support from WHO for countries to take action to reduce risks from AMR, and that both FAO and OIE produce useful guidance including a range of standards and guidelines for good practice. Delegates agreed for APHCA to facilitate obtaining external funding to support undertaking some longer-term actions in a number of APHCA member countries.

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Annex V

ACTIVITIES OF THE WORLD HEALTH ORGANISATION

Global Foodborne Infections Network (GFN)

GFN Strategic objective have been modified as the following:

To support Member States' capacity to strengthen national and regional integrated surveillance, investigation, prevention and control of foodborne and other enteric infections by:

i. promoting the benefits of integrated surveillance through the engagement of decision-makers;

ii. fostering multi-sectoral partnerships relevant to regional and country goals and needs;

iii. supporting Member States to generate data to drive evidence-based decision making to reduce the incidence of foodborne diseases.

At its Annual September 2012 Meeting in Lyon, France, the GFN Steering Committee took on the challenge of outlining its' accountability roadmap and planning its' future Performance Measurement Framework. Related meeting outcomes included: the development of GFN performance measurement group and organizational templates; the re-alignment of GFN goals and; support for the development of GFN training needs and governance criteria. Performance measurement framework meeting outcomes included: the need for a GFN governance document; the identification of three GFN core activity areas in training, mentoring and communications; the development and monitoring of a yearly operational planning document to align yearly GFN activities with GFN's final performance measurement framework and; a GFN budget that outlines total funding by partner as well as yearly GFN costs.

OIE and WHO are exploring how to work together more closely on capacity building activities and efforts are being made to participate in each other's activities as a first step with an option to improve joint activities on laboratory, epidemiology and AMR capacity building in countries.

Expert Consultation on the Global View of Campylobacteriosis

A WHO Expert Consultation on the Global View of Campylobacteriosis was organized in collaboration with FAO and OIE hosted by the WHO Collaborating Centre for Reference and Research on Campylobacter, Utrecht University, Netherlands on 9-11 July 2012. The objectives were 1) to review the progress made since the previous two consultations, note successful approaches and lessons learned and identify challenges in controlling Campylobacter from farm to table and reducing the human health burden and attributable health consequences; 2) to consider cross-cutting areas, such food and waterborne campylobacteriosis and antimicrobial resistance, and take into account the context of both developed and developing countries: 3) to provide options for the WHO, FAO and OIE for developing ways forward to reduce Campylobacter in the food chain and the burden of foodborne campylobacteriosis. The meeting was organized under the following thematic areas: 1) burden of disease and health impact; 2) surveillance, antimicrobial resistance; 3) source attribution; 4) impact of control measures.

The consultation report will be published shortly and will present discussions, future steps and options for lowering the burden of foodborne and waterborne campylobacteriosis and associated antimicrobial resistance.

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Antimicrobial Resistance: Critically Important Antimicrobials for Human Health and WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR)

The World Health Organization (WHO) has developed and applied criteria to rank antimicrobials according to their relative importance in human medicine. Clinicians, regulatory agencies, policy-makers and other stakeholders can use this ranking when developing risk management strategies for the use of antimicrobials in food production animals. The use of the list will help preserve the effectiveness of currently available antimicrobials. The list was developed in Canberra in 2005 and has been subsequently re-examined and updated during WHO expert meetings in Denmark in 2007 (1st revision) and in 2009 (2nd revision), and lastly in Oslo, Norway in 2011 (3rd revision). The WHO list is available at: www.who.int/foodborne_disease/resistance/cia/en

The WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (WHO-AGISAR, http://www.who.int/foodborne_disease/resistance/agisar/en/index.html) was established in December 2008 to support WHO's effort to minimize the public health impact of antimicrobial resistance associated with the use of antimicrobials in food animals. In particular, the Advisory Group will assist WHO on matters related to the integrated surveillance of antimicrobial resistance and the containment of food-related antimicrobial resistance. One of the main objectives of WHO-AGISAR is to promote harmonization of methods as well as data and experience sharing in the area of foodborne antimicrobial resistance at global level.

The WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance comprises over 30 internationally-renowned experts in a broad range of disciplines relevant to antimicrobial resistance, appointed following a web-published call for advisers, as well as representatives from FAO, OIE, EFSA and ECDC. WHO-AGISAR holds regular telephone conferences and annual face-to-face meetings. WHO-AGISAR 4th annual meeting took place in June 2012 in Aix-en-Provence, France and was attended by OIE staff and experts.

WHO-AGISAR contribute to enhancing the capacity of Member States, particularly developing countries, through training courses (using the GFN training platform), focused research projects and country sentinel studies.

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NB: At the joint High Level Meeting to Address Health Risks at the Human-animal-ecosystems Interface (November, 2011; http://www.who.int/influenza/human_animal_interface/HLTM_human_animal_ecosystems_nov_2011.pdf), AMR was highlighted as an "entry point" for many of the discussions (along with rabies and zoonotic influenza). These health issues were selected as there is already existing experience and best practices on how to address them cross-sectorally which could be used to develop approaches for other health issues at the interface, and also because they were deemed as important in and of themselves for ongoing tripartite focus.

* * *

Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA)

The 42nd Session of the Codex Committee on Food Hygiene (CCFH) held in December 2010 requested FAO and WHO to review the current status of knowledge of parasites in food to better assess the global problem associated with these, the commodities involved and the related public health and socio-economic/trade issues to identify parasite/commodity groups of greatest concern. In order to address this request FAO and WHO initiated a series of activities this culminated in an expert meeting on 3-7 September 2012. Preceding the meeting, relevant data were identified and collated through a formal "call for data", a literature review and written reports prepared by experts representing different regions. A list of 95 potential foodborne parasites was initially identified for consideration. Through a stepwise documented process this was reduced to a list of 24 parasites for ranking. Experts further identified specific vehicles of transmission for each of the 24 parasites. The parasites were ranked using a multicriteria-based approach, which used 9 criteria and 7 criteria weights (three criteria for disease severity were combined into one criterion) reflecting the relative importance of each criterion to the overall score. The overall score for each parasite was calculated by normalized parasite criteria scores multiplied by fractional weights and summed. The meeting also concluded that since criteria weights were calculated separately from the individual parasite scoring, alternative weighting schemes reflecting the judgments of risk

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managers could be used to generate alternate ranking, using the scoring of the parasites undertaken by the expert meeting. Furthermore, the meeting highlighted some considerations for risk management including knowledge on foodborne attribution and possible approaches for the control of some of these foodborne parasites. Reference is also made to existing risk management texts as appropriate. The preliminary report is available at http://www.fao.org/food/food-safety-quality/a-z-index/foodborne-parasites/en/ and http://www.who.int/foodsafety/micro/jemra/meetings/sep12/en/index.html. In addition, according to requests from the 43rd Session of the CCFH held in December 2011, FAO and WHO have been conducting peer-review of risk profiles for *Trichinella* spp. and *Cysticercus bovis* by selected experts in the area of parasitology, and preparing for development of risk-based examples for them to illustrate the level of consumer protection likely to be achieved with different post-harvest risk management options, depending on the availability of data and information.

More details on the recent JEMRA activities can be found at ftp://ftp.fao.org/codex/meetings/CCFH/CCFH44/fh44_04e.pdf.

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The Foodborne Disease Burden Epidemiology Reference Group (FERG)

From 7 to 10 November 2011, WHO hosted the strategic planning meeting of the Foodborne Disease Burden Epidemiology Reference Group (FERG) in Durres, Albania, combined with a kick-off event of the FERG pilot foodborne disease burden studies. The objectives of the strategic planning meeting were in view of the increased complexity of the WHO Initiative to Estimate the Global Burden of Foodborne Diseases as well as the changed environment in which the Initiative is operating, to:

- update the Initiative's strategic framework, its milestones and timelines;
- redefine the technical scope of the Initiative, including the selection of priority areas for foodborne disease burden estimation;
- identify key activities and resource needs for implementation; and
- update FERG processes, roles and responsibilities.

Following the strategic planning meeting, a new FERG Computational Task Force was established in March 2012 to advise and assist WHO and its Member States to convert results of (a) the global epidemiological reviews for mortality, morbidity and disability in each of the major foodborne diseases and (b) epidemiological data resulting from the FERG country studies into DALYs. This task force met in October 2012 for the first time to revise the task force's work plan and appraise the progress of the six Task Force subgroups made so far.

In 2012, the FERG pilot foodborne disease burden studies in Albania, Japan, Thailand and Uganda took up speed and, with the technical support of the FERG Country Studies Task Force, progressed well according to the national contexts. A needs assessment for food safety situation analysis and knowledge translation is, moreover, currently being undertaken by the FERG to develop targeted capacity building modules for the four pilot countries.

Works commenced by FERG in the areas of aflatoxicosis, peanut allergies, human trichinellosis and foodborne trematodiases were furthermore published in the peer-reviewed literature (articles available on our website at http://www.who.int/foodsafety/foodborne_disease/ferg/en/index7.html).

It is foreseen for the FERG to have finalized its work by the end of 2013, with the aim to officially present the FERG's results at an event in early 2014.

For more information please contact foodsafety@who.int.

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Promoting health by decreasing microbial contamination

WHO has extended the Five Keys to Safer Food concept to cover additional groups across the farm to table continuum to promote safe food handling practices. The manual Five keys to growing safer fruits and vegetables: promoting health by decreasing microbial contamination is designed to support food safety education of rural workers who grow fresh fruits and vegetables for themselves, their families and for sale in local markets. The manual describes key practices and raises awareness of the links between the health of humans, animals and the environment and how failures in good hygienic practices in one sector can affect the others.

The final edition of the manual (pilot tested in Belize, Guatemala y El Salvador) is available in English, French and Spanish at http://www.who.int/foodsafety/consumer/5keys_growing_safer/en/index.html

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The International Food Safety Authorities Network (INFOSAN)

INFOSAN is a joint FAO/WHO initiative which includes the participation of 178 Member States. The aim of the network is to promote the rapid exchange of information during food safety related events, share information on important food safety related issues of global interest, promote partnership and collaboration between countries, and help countries strengthen their capacity to manage food safety emergencies. To accomplish this, INFOSAN works with a number of partners at the international and regional level. INFOSAN receives information from its members and monitors for food safety related events of potential international concern to alert to its network members. During the past year, the INFOSAN Secretariat has been involved in the coordination of information between network members during dozens of food safety events with potential international implications.

Following the first global meeting of INFOSAN in 2010, a number of the resulting recommendations to enhance communication and collaboration among members have since been implemented. One such recommendation was to improve the web-based information-sharing mechanism. Since the meeting, the INFOSAN Community Website was developed and launched in 2012, and provides a platform for exchanging routine and emergency food safety information between INFOSAN Members. Another strong recommendation coming from the global meeting was to develop regionally based strategies to strengthen INFOSAN participation. We have since worked with our colleagues from WHO-WPRO and INFOSAN members in Asia to develop a regional strategy to enhance participation in INFOSAN among Asian countries. While INFOSAN is indeed a global network, addressing specific regional needs can help to strengthen the network overall.

We have also been focusing this year on expanding our membership and asking member countries to nominate additional Focal Points from the various national authorities with a stake in food safety. In relation to this task, the INFOSAN Secretariat has extended INFOSAN membership to include OIE National Focal points for Food Safety in order to further strengthen cross-sectoral coordination and cooperation at national and global levels.

Several tools to provide guidance in dealing with food safety emergencies have been or are being developed, which will help Member States in the strengthening of their national systems, the most recent of which is about establishing or improving national food recall systems. These documents are published on our website.

For more information, please visit: http://www.who.int/foodsafety/fs_management/infosan/en/index.html

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WORK PROGRAMME FOR 2013

The Working Group agreed that its work programme for 2013 would include:

1. Horizontal issues

   a) Antimicrobial resistance.

   b) The *ad hoc* Group on Vaccines in Relation to New and Emerging Technologies – animals and animal products derived from biotechnological interventions – review texts for potential food safety implications of biotechnology vaccines when this work is undertaken. Follow any developments in nanotechnology relevant to the work of the Working Group.

   c) Animal production food safety in veterinary education.

   d) Animal production food safety in veterinary legislation.

   e) Food safety issues arising from the on-going work on zoonoses at the human animal ecosystem interface ('One Health').

   f) Evaluating performance of competent authorities including Veterinary Services.

2. Disease-specific issues

   a) *Terrestrial Code* chapter on brucellosis.

   b) *Terrestrial Code* chapter on *Trichinella* infection and linkages to on-going Codex work.

   c) *Terrestrial Code* chapter on porcine cysticercosis.

   d) *Terrestrial Code* chapter on echinococcosis/hydatidosis.

   e) Potential standard development on *Salmonella* in intensive pig production ensuring a whole food chain approach and linkages to any Codex work.

   f) Follow up of literature review on verotoxigenic *Escherichia coli* (VTEC/STEC)

   g) Generic aspects of food safety control systems associated with contamination with enteric pathogens and linkages to Codex work.

   h) Generic aspects of food safety control systems associated with parasites and linkages to Codex work.

3. Relationship between OIE and Codex

   a) Encourage enhanced OIE input into Codex texts and vice versa.

   b) Encourage continued close collaboration between the Codex Secretariat and the OIE Headquarters.

   c) Identification of areas where closer collaboration between OIE and Codex on the development of standards could be desirable.

   d) Follow up on the work of the Codex Committee on General Principles (CCGP) electronic Working Group on Codex/OIE Cooperation.

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Annex XLIV

FUTURE WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Topic		
Action	**How to be managed**	**Status (Feb 2013)**
Restructuring of the *Terrestrial Code*, including Harmonisation of the *Terrestrial* and *Aquatic Codes*		
1. Work with AAHSC towards harmonisation, as appropriate, of the Codes 2. CH rename by disease agents 3. Revision and formatting of Section 7 4. Revision of the Users' guide 5. OIE policy on wildlife	TAHSC & ITD3.TAHSC & AWWG 4. TAHSC & SCAD 5. TAHSC with WG on Wildlife & SCAD	1. Ongoing, revised CH 1.1. for adoption 2. Ongoing 3. Revised 7.5 and 7.6. for MC 4 Revised User's Guide for MC 5. Ongoing
Notification of 'emerging disease'		
Clarification of definition, criteria for notification, etc.	SCAD & TAHSC	Ongoing
Listed diseases		
1. Criteria for listing 2. List of diseases	TAHSC & SCAD	1. Revised CH 1.2. for adoption 2. Revised list for adoption
CWD		
Decision on listing (new CH)	TAHSC & SCAD & AHG	AHG to be convened
PRRS		
New CH	SCAD/AHG	AHG to be convened
Evaluation of VS and OIE PVS pathway		
Veterinary education aspect	TAHSC & AHG & ITD	Ongoing
CSF		
Official recognition CSF	SCAD/AHG & TAHSC	Revised CH 15.2. for adoption
AHS		
Official recognition - zones	SCAD & TAHSC	Revised CH 12.1. for adoption
PPR		
Update CH on PPR including official recognition	SCAD & TAHSC	Revised CH 14.8. for adoption
FMD		
Revise chapter including wildlife	SCAD & TAHSC	Revised CH 8.5. for MC
RP		
Global freedom era	SCAD & TAHSC	Revised CH 8.12 for adoption
New horizontal chapter on disease control		
Draft new chapter	SCAD & TAHSC	Draft new CH for MC
Horse diseases		
1. International movement of competition horses 2. Update horse disease chapters	AHG/SCAD & TAHSC	AHG to be convened

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Annex XLIV (contd)

Veterinary products (AMR)		
1. Updating CH 6.9. 2. Updating CH 6.10.	TAHSC & SCAD & AHG	1. Revised CH 6.9. for adoption 2. Revised CH 6.10. for MC
Other *Terrestrial Code* texts on diseases in need of revision		
Pet food certificate CH	TAHSC	On hold
Update BT and EHD in line with AHS	SCAD & AHG	AHG to be convened
Update CH on Brucellosis	AHG/SCAD & TAHSC	Revised CH 8.X. for MC
Update CH on Rabies (article on control of rabies in dog)	SCAD & TAHSC	Revised CH 8.10. for adoption
Update CH on Bee diseases	AHG/SCAD & TAHSC	Revised CHs for adoption
CH on EHD	SCAD & TAHSC	Revised new chapter for MC
Update CH on SVD	SCAD & TAHSC	Delisting proposed for adoption
Update CH on ASF (SURV)	SCAD	Pending SCAD revision
CH on Paratuberculosis	BSC (diagnostic test) & STD (guidance document)	Ongoing
Update CH on tuberculosis	AHG/SCAD & TAHSC	AHG to be convened
Update CH on Avian Mycoplasmosis	SCAD and TAHSC	Pending SCAD revision

Animal production food safety		
2. Zoonotic parasitic diseases a. *Trichinella* spp. b. Echinococcosis c. *Taenia solium* (Porcine cysticercosis)	AHG & TAHSC	a. Revised CH 8.13 for adoption b. Revised CH8.4 and X.X. for adoption c. On hold pending delisting
Animal welfare		
New texts: 1. Broiler production systems 2. Dairy cattle production systems	AWWG & AHGs TAHSC supervision	1. New CH 7.X for adoption 2. New CH for MC

Note: MC; Member comments, CH: chapter, Q: questionnaire, SURV: surveillance, ITD: International Trade Department, S&T Dept: Scientific & Technical Department

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ITEM, ANNEX, CHAPTER NUMBERS AND CURRENT STATUS

Item	Annex	Chapter	Title	Provided for comments	GS81
1			General comments		
2	XXXII		User's Guide	Feb. 13	C
3	IV		Glossary	Sep. 12	A
4	V	1.1.	Notification of diseases and epidemiological information	Sep. 12	A
5	VI	1.2.	Criteria for listing diseases		A
		8.15.	Vesicular stomatitis		
		15.4.	Swine vesicular disease		
	XXXIII		Report of electronic *ad hoc* Group on listing *Taenia solium*		I
6	VII	3.2.	Evaluation of veterinary services	Sep. 12	A
	VIII	3.4.	Veterinary legislation	Sep. 11	A
	XXXIV		Report of *ad hoc* Group on Veterinary Legislation		I
7	IX	4.6.	Collection and processing of bovine, small ruminant and porcine semen	Sep. 12	A
		4.7.	Collection and processing of *in vivo* derived embryos from livestock and horses		
8	X	6.4.	Biosecurity procedures in poultry production	Sep. 12	A
9		6.6.	Introduction to the recommendations for controlling antimicrobial resistance	Sep. 12	D
		6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	Sep. 12	D
	XI	6.9.	Responsible and prudent use of antimicrobial	Sep. 11	A
	XXXV	6.10	Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals	Feb. 12	C
10	XII	6.11.	Zoonoses transmissible from non-human primates	Sep. 12	A
11	XIII	NEW	Broiler chicken production systems	Sep. 10	A
	XIV	7.1.	Introduction to the recommendation for AW (General principle for production system)	Sep. 11	A
	XV	7.9.	Beef cattle production systems	Sep. 12	A
	XVI	7.8.	Use of animals in research and education	Sep. 12	A
	XXXVI	7.5 & 7.6.	Revision of AW chapters	Feb. 13	C
	XXXVII	NEW	Dairy cattle production systems	Feb. 13	C
			Report of *ad hoc* Group on AW and Dairy cattle production systems		I
	XXXVIII		AWWG work programme	Feb. 13	I
12		8.3.	Bluetongue	Sep. 11	D
13	XVII	8.4.	Echinococcosis (*E. granulosus*)	Feb. 11	A
		NEW	Echinococcosis (*E. multilocularis*)	Feb. 11	
	XVIII	8.13.	*Trichinella* infection	Feb. 11	A

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Annex XLIV (contd)

Item	Annex	Chapter	Title	Provided for comments	GS81
14	XXXIX	8.5.	Foot and mouth disease	Feb. 13	C
15	XIX	8.10.	Rabies		A
16	XX	8.12.	Rinderpest	Sep. 11	A
17	XXI	4.14.	Official health control of bee diseases	Sep. 12	A
	XXII	9.1. 9.2. 9.3. 9.4. 9.5. 9.6.	Acarapisosis of honey bees American foulbrood of honey bees European foulbrood of honey bees Small hive beetle infestation (*Aethina tumida*) *Tropilaelaps* infestation of honey bees Varroosis of honey bees	Sep. 09	A
18	XXIII	10.4.	Infection with avian influenza viruses	Sep. 12	A
19	XXIV	10.9.	Newcastle disease		A
20	XL	11.3.	Brucellosis	Sep. 11	C
21	XXV	1.6.	Procedure for self declaration and for official recognition by the OIE	Sep. 12	A
		11.5.	Bovine spongiform encephalopathy		
22	XXVI	11.8.	CBPP	Sep. 12	A
23	XXVII	12.1.	Infection with African horse sickness virus		A
	XXVIII	12.9.	Infection with equine arteritis virus		A
24	XXIX	14.5.	Infection with *Chlamydophila abortus*	Sep. 12	A
25	XXX	1.6.	Procedure for self declaration and for official recognition by the OIE		A
		14.8.	Peste des petits ruminants	Sep. 11	
26	XXXI	1.6.	Procedure for self declaration and for official recognition by the OIE		A
		15.2.	Classical swine fever	Sep. 10	
27	XLI	New	Epizootic haemorrhagic disease	Sep. 12	C
28	XLII	New	Disease control	Feb. 13	C
29	XLIII		Report of APFSWG		I
30	XLIV		Work programme		C
31			Review of application for recognition as an OIE collaboration centre		
32			Inactivation of pathogen in casings		
33		11.12.	Lumpy skin disease		E

A: proposed for adoption at 81th General Session, C: For Member comments, E: under expert consultation (*ad hoc* Groups, Specialist Commissions etc.), D: deferred to Sep 2013 meeting, I: For Member information.

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHS	African horse sickness
APFSWG	Animal Production Food Safety Working Group
AWWG	Animal Welfare Working Group
EHD	Epizootic haemorrhagic disease
FMD	Foot and mouth disease
PPR	Peste des petits ruminants
PRRS	Porcine reproductive and respiratory syndrome
SCAD	Scientific Commission for Animal Diseases
TAHSC	Terrestrial Animal Health Standards Commission
VE	Veterinary Education

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